Spikevax

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/0120	Submission of the final report from study mRNA-1273-P301; this is a Phase 3, randomised, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of Spikevax in adults aged 18 years and older, listed as a category 3 study in the RMP. The RMP version 8.2	11/04/2024	n/a		

[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).

	has also been approved. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
PSUSA/10897 /202306	Periodic Safety Update EU Single assessment - elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), andusomeran (Spikevax XBB.1.5)	25/01/2024	21/03/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10897/202306.
IB/0125	B.I.b.z - Change in control of the AS - Other variation	20/03/2024	n/a		
II/0116/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch	07/03/2024	n/a		

	release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing				

	processes B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products				

IAIN/0122/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	30/01/2024		SmPC, Annex II, Labelling and PL	
IB/0118/G	This was an application for a group of variations. B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	15/12/2023	n/a		
II/0114/G	This was an application for a group of variations. C.I.4 (Type II): Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC to update the safety information regarding the administration of Spikevax to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, based on updated clinical literature and internal data; the Package Leaflet is updated accordingly. C.I.Z (Type IB): To update section 6.6 of the SmPC	14/12/2023	21/03/2024	SmPC and PL	The safety, reactogenicity, and immunogenicity of Spikevax (original) were evaluated in a two-part Phase 3b open-label study in adult solid organ transplant (SOT) recipients, including kidney and liver transplants (mRNA-1273-P304). A 100 microgram (0.5 mL) dose was administered, which was the dose authorised at the time of study conduct. In Part A, 128 SOT recipients received a third dose of Spikevax (original). In Part B, 159 SOT recipients received a booster dose at least 4 months after the last dose (fourth dose for mRNA vaccines and third dose for non-mRNA vaccines). Reactogenicity was consistent with the known profile of Spikevax (original). There were no unexpected safety findings.

	in order to clarify the handling instructions for the pre-filled syringes; the Package Leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				For more information, please refer to the Summary of Product Characteristics.
II/0110	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/10/2023	n/a		
IB/0115	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	23/10/2023	n/a		
N/0117	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/10/2023	21/03/2024	PL	
II/0111/G	This was an application for a group of variations. B.I.a.6.a - Changes to the active substance of a vaccine against human coronavirus - 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 B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	14/09/2023	15/09/2023	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Spikevax-H-C-005791-II-0111-G'.

	Replacement/addition of a site where batch control/testing takes place B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.I.a.6.a - Changes to the active substance of a vaccine against human coronavirus - 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 B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation				
IB/0112/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	08/09/2023	n/a		

	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor				

	changes to an approved test procedure B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
II/0100/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release -	31/08/2023	n/a		

	Not including batch control/testing B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes				
II/0094/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	31/08/2023	n/a		

	B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				

PSUSA/10897 /202212	Periodic Safety Update EU Single assessment - elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), andusomeran (Spikevax XBB.1.5)	20/07/2023	29/08/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10897/202212.
IB/0107	B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	14/08/2023	n/a		
II/0104/G	This was an application for a group of variations. C.I.6.a: Extension of indication to include the use of Spikevax bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL dispersion for injection in children 6 months through 4 years of age, based on data from study mRNA-1273-P306 (NCT05436834) part 1; this is an Open-Label, Phase 3 Study to Evaluate the Safety and Immunogenicity of the mRNA-1273.214 (Original/Omicron BA.1) vaccine for SARS-CoV-2 in participants aged 6 months to < 6 years; as a consequence, sections 4.1 and 4.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.1 of the RMP has been approved. C.I.6.a: Extension of indication to include the use of Spikevax bivalent Original/Omicron BA.4-5 (all presentations) as a single-dose in individuals 5 years of age and older, irrespective of their vaccination history, based on epidemiology and clinical data from	20/07/2023	11/08/2023	SmPC, Labelling and PL	Please refer to Scientific Discussion Spikevax H-C-005791-II-0104-G.

	study mRNA-1273-P306; as a consequence, section 4.2 of the SmPC is updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to make minor editorial changes throughout the SmPC, Annex II, labelling and package leaflet. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0109/G	This was an application for a group of variations. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	03/07/2023	n/a		
IB/0108	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	30/06/2023	n/a		
IB/0102/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of	06/06/2023	n/a		

	the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits				
IB/0105/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	05/06/2023	n/a		
IB/0099/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of	31/05/2023	n/a		

	the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change				

	in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
II/0097/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/04/2023	26/05/2023	SmPC, Labelling and PL	Please refer to Scientific Discussion 'Spikevax-H-C-005791-II-97-G'
IB/0103/G	This was an application for a group of variations. B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation	15/05/2023	n/a		
II/0085/G	This was an application for a group of variations. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated	12/05/2023	n/a		

	by new additional data to be submitted by the MAH where significant assessment is required C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IA/0101/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.6 - Administrative change - Change in ATC Code/ATC Vet Code	11/04/2023	26/05/2023	SmPC, Annex II and PL	The SmPC is updated to update the ATC code. Annex II is updated to remove the QC exemption.
II/0088	Submission of the final report from study DMID 20-0003 listed as a category 3 study in the RMP. This is a Phase I, Open Label, Dose-ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults. This submission fulfils the post-authorisation measure MEA 007.3. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	30/03/2023	n/a		
II/0093	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	16/03/2023	n/a		
IA/0096/G	This was an application for a group of variations. B.II.b.5.b - Change to in-process tests or limits	01/03/2023	n/a		

	applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change				

	in the manufacturing process B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.I.a.1.z - Change in the manufacturer of AS or of a				

	starting material/reagent/intermediate for AS - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
IB/0095	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	07/02/2023	n/a		
PSUSA/10897 /202206	Periodic Safety Update EU Single assessment - elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), andusomeran (Spikevax XBB.1.5)	12/01/2023	n/a		PRAC Recommendation - maintenance
II/0090/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new	15/12/2022	16/12/2022	SmPC, Labelling and PL	

	container - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method				
II/0089/G	This was an application for a group of variations. B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes	15/12/2022	16/12/2022	SmPC, Labelling and PL	

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method				
II/0083/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/12/2022	16/12/2022	SmPC, Labelling and PL	Please refer to Scientific Discussion 'Spikevax-H-C-005791-II-83-G'

IB/0092	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	08/12/2022	n/a		
IAIN/0091	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	02/12/2022	02/12/2022	SmPC and PL	To update section 4.8 of the SmPC and section 4 of the PL to implement the signal recommendation on heavy menstrual bleeding.
II/0077	Update of section 4.8 of the SmPC to include 'Urticaria' as an adverse reaction, with the frequency 'Uncommon', as requested by the PRAC in the 13th Safety Summary Report (EMEA/H/C/005791/MEA/011.12). The Package Leaflet is updated accordingly. C.I.3.b - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Change(s) with new additional data submitted by the MAH	27/10/2022	10/11/2022	SmPC and PL	SmPC new text Urticaria (raised, itchy rash) has been observed with either acute onset (within a few days after vaccination) or delayed onset (up to approximately two weeks after vaccination), with the frequency 'Uncommon'. For more information, please refer to the Summary of Product Characteristics.
II/0087/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.1.c - Replacement or addition of a	04/11/2022	n/a		

	manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The				

	change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol				

	product and any of the test methods at the site is a biol/immunol method				
IB/0086	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	25/10/2022	n/a		
II/0084/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.I.a.6.a - Changes to the active substance of a vaccine against human coronavirus - 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 B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	19/10/2022	20/10/2022	SmPC, Annex II, Labelling and PL	
II/0067	Extension of indication to include immunisation of paediatric individuals from 6 months through 5 years of age based on results from the study P204 (KidCove); this is a phase 2/3, two-part, open-label, dose-escalation, age de-escalation and randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity, and effectiveness of mRNA-1273 SARS-CoV-2	19/10/2022	20/10/2022	SmPC and PL	Please refer to Scientific Discussion 'Spikevax-H-C-005791-II-0067'

	vaccine in healthy children 6 months to less than 12 years of age. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC are updated and the Package Leaflet is updated in accordance. The MAH also took the opportunity to implement minor editorial changes in the product information. A revised RMP version 4.1 has been approved. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0076/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	13/10/2022	n/a		

	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol				
IB/0082	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	10/10/2022	n/a		
II/0079/G	This was an application for a group of variations. B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing	06/10/2022	20/10/2022	SmPC, Annex II, Labelling and PL	

	processes B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
II/0078/G	This was an application for a group of variations. B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue	06/10/2022	20/10/2022	SmPC, Labelling and PL	
R/0074	Renewal of the marketing authorisation.	15/09/2022	03/10/2022	SmPC, Annex II and PL	
IB/0081/G	This was an application for a group of variations. B.II.c.4.a - Change in synthesis or recovery of a non-	21/09/2022	n/a		

	pharmacopoeial or novel excipient - Minor change B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation B.II.c.4.a - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Minor change B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation				
II/0066	Update of section 4.5 of the SmPC in order to indicate the possibility of co-administration of Spikevax with a high-dose quadrivalent influenza vaccine, based on the interim results from study QHD00028 (NCT04969276), a Phase II, open-label study aimed to assess the safety and immunogenicity of a high-dose quadrivalent influenza vaccine (2021-2022 formulation) and a third dose of Spikevax administered either concomitantly or singly in adults 65 years of age and older previously primed with Spikevax. The MAH is taking the opportunity to include as editorial updates in sections 5.1 and 6.6 of the SmPC, Annex II and package leaflet, corrections from procedure EMEA/H/C/005791/II/0075. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/09/2022	16/09/2022	SmPC, Annex II and PL	Eligible participants, who received 2 doses of Spikevax at least 5 months before enrolment in the study, were randomly assigned to 1 of 3 vaccination groups: i) concomitant administration of the high-dose influenza and Spikevax vaccines, ii) administration of high-dose influenza vaccine alone, and iii) administration of Spikevax vaccine alone. The immunogenicity responses against influenza were in general comparable between the concomitant group and the vaccine group that received high-dose influenza alone, with only a minimal, if any, trend towards higher results in the high-dose influenza alone vaccine group. This trend was not considered of clinical relevance. The immunogenicity responses against SARS-CoV-2 were also comparable with a minimal trend towards higher geometric mean titres in the Spikevax alone vaccine group as compared to the concomitant group, which was not deemed of clinical relevance. No evidence of an adverse impact on the safety profile after concomitant administration of high-dose influenza and Spikevax vaccines was observed. The study was carried out with a 100 µg dose of Spikevax, instead of 50 µg as approved. Nevertheless the study design per se was deemed adequate to investigate an impairment of the immune

					response after co-administration, independent of the dose, while creating a considerable safety margin when following the current booster recommendation.
II/0075/G	This was an application for a group of variations. B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.I.d.1.a.3 - Stability of AS - Change in the re-test period/storage period - Extension of storage period of a biological/immunological AS not in accordance with an approved stability protocol B.I.d.1.b.2 - Stability of AS - Change in the storage conditions - Change in storage conditions of biological/immunological ASs, when the stability studies have not been performed in accordance with a currently approved stability protocol B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical	01/09/2022	01/09/2022	SmPC, Annex II, Labelling and PL	

	forms manufactured by complex manufacturing processes B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.6.a - Changes to the active substance of a vaccine against human coronavirus - 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 B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy				

	of the medicinal product B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS				
X/0065	Annex I_2.(c) Change or addition of a new strength/potency	21/07/2022	16/08/2022	SmPC, Annex II, Labelling and PL	
X/0064	Annex I_2.(c) Change or addition of a new strength/potency	21/07/2022	16/08/2022	SmPC, Annex II, Labelling and PL	
PSUSA/10897 /202112	Periodic Safety Update EU Single assessment - elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), andusomeran (Spikevax XBB.1.5)	21/07/2022	16/08/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10897/202112.
II/0057	Update of sections 4.2 and 4.4 of the Spikevax SmPC to include a 50 µg booster dose for adolescents 12 to 18 years of age, based on the extrapolation of safety and efficacy data from young adults (18 to 24 years of age). The package leaflet is updated accordingly. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/07/2022	16/08/2022	SmPC and PL	A booster dose of Spikevax should be given intramuscularly to individuals 12 years of age and older at least 3 months after completion of the primary series. Myocarditis and pericarditis have been observed more often after the second dose compared to the first dose, and more often in younger males. The risk profile appears to be similar for the second and the third dose. For more information, please refer to the Summary of

					Product Characteristics.
IB/0072	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	20/07/2022	16/08/2022	SmPC	Update of section 6.3 of the SmPC to state that stability has been demonstrated for 12 months when Spikevax is stored under certain conditions.
II/0073	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	12/07/2022	16/08/2022	Annex II	
II/0062	Submission of an updated RMP version 4.0 in order to remove 'anaphylaxis' as an important identified risk; to remove 'interaction with other vaccines' as a safety concern in study mRNA-1273-P904 following the outcome of the EMEA/H/C/005791/MEA/004.4 procedure; to implement the WHO-approved INN 'elasomeran'; to update the study milestones for the mRNA-1273-P301, mRNA1273-P203, mRNA-1273-P201, mRNA-1273-P901, mRNA-1273-P903 and mRNA-1273-P910 studies and to add study mRNA-1273-P911 to the RMP. The Annex II of the Product Information is updated accordingly. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	23/06/2022	16/08/2022	Annex II	

IA/0070/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	15/06/2022	16/08/2022	Annex II	
IB/0069	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	14/06/2022	n/a		
IB/0071	B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	01/06/2022	n/a		
IB/0061/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test A.7 - Administrative change - Deletion of manufacturing sites	24/05/2022	n/a		

	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
IAIN/0068	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	05/05/2022	16/08/2022	Annex II, Labelling and PL	To change the address of the site responsible for batch release.
II/0050	B.II.b.z - Change in manufacture of the Finished Product - Other variation	28/04/2022	n/a		
IAIN/0063/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation A.1 - Administrative change - Change in the name and/or address of the MAH	25/04/2022	29/04/2022	SmPC, Labelling and PL	To update section 4.4 of the SmPC and section 2 of the PL to implement information on the capillary leak syndrome. The address of the MAH has also been updated.
IB/0060	B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	31/03/2022	n/a		
II/0059	Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment	25/03/2022	29/04/2022	Annex II	

	is required C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
II/0038/G	This was an application for a group of variations. B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.2.z - Change in test procedure for an excipient - Other variation B.II.c.2.z - Change in test procedure for an excipient - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation	24/03/2022	n/a		
II/0054/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	10/03/2022	n/a		

	B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability				
II/0047	Update of section 5.1 of the SmPC in order to introduce data on the immunogenicity of Spikevax against the B.1.617.2 (Delta) variant in adults and children, based on cross-neutralisation data from studies mRNA-1273-P301 (an ongoing Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older - NCT04470427), mRNA-1273-P201B (Part B of an ongoing Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older - NCT04405076), and mRNA-1273-P204 (an ongoing Phase 2/3, 2-part, open-label, dose-escalation, age de-escalation and subsequent randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity, and effectiveness of mRNA-1273 in healthy children - NCT04796896).	24/02/2022	02/03/2022	SmPC	SmPC new text Pre-boost and post-boost neutralising antibody against the B.1.617.2 (Delta) variant in adults Results of the pseudovirus neutralisation assay (PsVNA) against the B.1.617.2 (Delta) variant determined pre-booster and on Day 29 post booster showed that administration of a booster dose of Spikevax (0.25 mL, 50 micrograms) in adults induced a 17 fold rise in neutralising antibodies against the Delta variant compared with pre-booster levels (GMFR = 17.28; 95% CI: 14.38, 20.77; n=295). Neutralising antibody against the B.1.617.2 (Delta) variant in children 6 through 11 years of age Serum samples of the per-protocol immunogenicity subset (n=134) of the ongoing paediatric study obtained at baseline and on Day 57 were tested in a PsVNA based on the B.1.617.2 (Delta) variant. In children 6 through 11 years of age, the GMFR from baseline to D57 was 81.77 (95% CI: 70.38, 95.00) for the

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				Delta variant (measured by PsVNA). Furthermore, 99.3% of children met the definition of seroresponse. For more information, please refer to the Summary of Product Characteristics.
II/0042	Update of sections 4.2 and 5.1 of the SmPC in order to include information on heterologous boosting using a 50 ug dose of Spikevax to boost subjects that have previously completed a primary vaccination series with any authorised COVID-19 vaccine, and to shorten the duration of the interval between the primary series and the booster dose to 3 months, based on data from the DMID Study 21-0012, a Phase 1/2 heterologous SARS-CoV-2 vaccine dosing (mRNA-1273 booster) study of the various vaccines authorized in the US under Emergency Use Authorisation in participants ≥ 18 years old (NCT04889209). In addition, the MAH took the opportunity to implement the WHO-approved INN 'elasomeran' and make minor editorial changes/corrections throughout the product information. The Annex A, the Labelling and the Package Leaflet are amended accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	24/02/2022	02/03/2022	SmPC, Labelling and PL	SmPC new text A booster dose of Spikevax (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) should be given intramuscularly to adults at least 3 months after completion of the primary series. Spikevax may be used to boost adults who have received a primary series with Spikevax or a primary series comprised of another mRNA vaccine or adenoviral vector vaccine. Safety and immunogenicity of a heterologous booster with Spikevax were studied in an investigator-initiated trial with 154 participants. The minimum time interval between primary series using a vector based or RNA-based COVID-19 vaccine and booster injection with Spikevax was 12 weeks (range: 12 weeks to 20.9 weeks). The dose used for boosting in this study was 100 micrograms. Neutralising antibody titres as measured by a pseudovirus neutralisation assay were assessed on Day 1 prior to administration and at Day 15 and Day 29 after the booster dose. A booster response was demonstrated regardless of primary vaccination. Only short-term immunogenicity data are available; long-term protection and immunological memory are currently unknown. COV-BOOST is a multicentre, randomised Phase 2 investigator-initiated trial of third dose booster vaccination against COVID-19 with a subgroup to investigate detailed immunology. Participants were adults aged 30 years or

					older, in good physical health (mild to moderate well-controlled co-morbidities were permitted), who had received two doses of either Pfizer–BioNTech or Oxford–AstraZeneca (first dose in December 2020, January 2021 or February 2021), and were at least 84 days post second dose by the time of enrolment. Spikevax boosted antibody and neutralising responses and was well tolerated regardless of the prime series. The dose used for boosting in this study was 100 micrograms. Neutralising antibody titres as measured by a pseudovirus neutralisation assay were assessed on Day 28 after the booster dose.
II/0041	Extension of indication to include use in children 6-11 years of age for Spikevax, based on data from study mRNA-1273-P204, an ongoing Phase 2/3, 2-part, open-label, dose-escalation, age de-escalation and subsequent randomized, observer-blind, placebo-controlled expansion study to evaluate the safety, tolerability, reactogenicity, and effectiveness of mRNA-1273 in healthy children; as a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. Annex II and the Package Leaflet are updated in accordance. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	24/02/2022	02/03/2022	SmPC, Annex II and PL	Please refer to Scientific Discussion 'EMEA/H/C/005791/II/0041'
II/0052/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP -	24/02/2022	n/a		

	Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol				

	product and any of the test methods at the site is a biol/immunol method B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products				
II/0051/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	24/02/2022	n/a		
IB/0055/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test	18/02/2022	n/a		

	period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.II.f.1.e - Stability of FP - Change to an approved stability protocol 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 B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol				
IB/0056	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/02/2022	02/03/2022	SmPC and PL	To update section 4.6 of the SmPC and section 2 of the PL to implement the recommendation on vaccination with Spikevax in pregnant women and breastfeeding as requested by the CHMP.
IAIN/0053	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	15/02/2022	02/03/2022	Annex II and PL	
PSUSA/10897 /202106	Periodic Safety Update EU Single assessment - elasomeran (Spikevax), elasomeran / imelasomeran (Spikevax bivalent Original/Omicron BA.1), elasomeran / davesomeran (Spikevax bivalent Original/Omicron BA.4-5), andusomeran (Spikevax XBB.1.5)	27/01/2022	14/02/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10897/202106.

II/0046	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	10/02/2022	n/a		
II/0028	Submission of an updated RMP version 2.3 to include myocarditis and pericarditis as an important identified risk, as requested by PRAC as an outcome of the myocarditis and pericarditis signal assessment procedure. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	10/02/2022	n/a		
II/0022	Submission of an updated RMP version 2.3 to include clinical safety data from study mRNA-1273 P203 (NCT04649151), a Phase 2/3, randomised, observer-blind, placebo-controlled study evaluating the safety, reactogenicity, and effectiveness of the mRNA-1273 vaccine in healthy adolescents aged ≥ 12 to < 18 years. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing	10/02/2022	n/a		

	authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
IB/0049	B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue	28/01/2022	n/a		
IB/0048/G	This was an application for a group of variations. B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	22/12/2021	n/a		
II/0043/G	This was an application for a group of variations. B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study B.II.z - Quality change - Finished product - Other variation B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products	16/12/2021	n/a		

IB/0044/G	This was an application for a group of variations. 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 B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.f.1.e - Stability of FP - Change to an approved stability protocol	08/12/2021	08/12/2021	SmPC and PL	To update the shelf life from 7 to 9 months and to update the storage claim to remove the statement to not store on dry ice.
IAIN/0045	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/12/2021	08/12/2021	SmPC and PL	To update sections 4.4 and 4.8 of the SmPC and sections 2 and 4 of the PL to implement the signal recommendations on 'Signal assessment report on myocarditis and pericarditis with Spikevax
II/0024/G	This was an application for a group of variations. B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to OCABR B.I.b.1.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	25/11/2021	n/a		

	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR B.II.d.1.b - Change in the specification parameters				

	and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR				
IB/0039/G	This was an application for a group of variations. B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation	23/11/2021	n/a		
IAIN/0040	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	11/11/2021	11/11/2021	SmPC and PL	To update section 4.8 of the SmPC and section 4 of the PL to implement the signal recommendation on erythema multiforme.
II/0015/G	This was an application for a group of variations. Grouped variation to address PRAC requests raised in the 3rd Spikevax Monthly Safety Summary Report (MSSR) procedure (EMEA/H/C/005791/MEA/011.2): - Update of section 4.8 of the SmPC to include details regarding time to onset and duration of the delayed injection site reactions. The Package Leaflet is updated accordingly. - Update of section 4.8 of the SmPC to include "diarrhoea" as an adverse reaction, with the frequency 'Common'. The Package Leaflet is updated accordingly.	28/10/2021	03/11/2021	SmPC and PL	SmPC new text The median time to onset of injection site reactions was 9 days after the first injection, and 11 days after the second injection. Median duration was 4 days after the first injection, and 4 days after the second injection. For more information, please refer to the Summary of Product Characteristics.

	In addition, the Marketing Authorisation Holder (MAH) took the opportunity to make minor editorial changes. C.I.3.b - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Change(s) with new additional data submitted by the MAH				
II/0034	To update sections 2, 4.2, 4.4, 4.8, 5.1, 6.5 and 6.6 of the SmPC to include a booster dose for Spikevax, based on new clinical data from studies mRNA-1273-P201, a Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (NCT04405076), mRNA-1273-P301, an ongoing Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older (NCT04470427) and DMID 21-0012, a Phase 1/2 Study of Delayed Heterologous SARS-CoV-2 Vaccine Dosing (Boost) After Receipt of EUA Vaccines (NCT04889209). The labelling and the package leaflet are updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/10/2021	29/10/2021	SmPC, Labelling and PL	SmPC new text A booster dose (0.25 mL, containing 50 micrograms mRNA, which is half of the primary dose) of Spikevax may be administered intramuscularly at least 6 months after the second dose in individuals 18 years of age and older. The decision when and for whom to implement a third dose of Spikevax should be made based on available vaccine effectiveness data, taking into account limited safety data. The risk of myocarditis after a third dose (0.5 mL, 100 micrograms) or booster dose (0.25 mL, 50 micrograms) of Spikevax has not yet been characterised. The safety, reactogenicity, and immunogenicity of a booster dose of Spikevax are evaluated in an ongoing Phase 2, randomised, observer-blind, placebo-controlled, dose-confirmation study in participants 18 years of age and older (NCT04405076). In this study, 198 participants received two doses (0.5 mL, 100 micrograms 1 month apart) of the Spikevax vaccine primary series. In an open-label phase of this study, participants received a single booster dose (0.25 mL, 50 micrograms) at least 6 months after receiving the second dose of the primary series. The

					solicited adverse reaction profile for the booster dose was similar to that after the second dose in the primary series. A single booster dose was shown to result in a geometric mean fold rise (GMFR) of 12.99 (95% CI: 11.04, 15.29) in neutralising antibodies from pre-booster compared to 28 days after the booster dose. The GMFR in neutralising antibodies was 1.53 (95% CI: 1.32, 1.77) when compared 28 days post dose 2 (primary series) to 28 days after the booster dose. For more information, please refer to the Summary of Product Characteristics.
IB/0037/G	This was an application for a group of variations. B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.4.a - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Minor change	13/10/2021	n/a		
IB/0036	B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	06/10/2021	n/a		

II/0035	B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study	05/10/2021	n/a		
II/0031	Update of sections 4.2 and 4.4 of the SmPC in order to introduce a third dose of Spikevax in the primary vaccination schedule for individuals 12 years of age and older who are severely immunocompromised, based on published literature data; the Package Leaflet is updated accordingly. The MAH took the opportunity to make minor administrative and editorial corrections throughout the product information. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	04/10/2021	05/10/2021	SmPC and PL	SmPC new text A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised. The recommendation to consider a third dose (0.5 mL) is based on limited serological evidence with patients who are immunocompromised after solid organ transplantation. For more information, please refer to the Summary of Product Characteristics. Please refer to Scientific Discussion 'Spikevax/H/C/005791/II/31'
R/0025	Renewal of the marketing authorisation.	16/09/2021	04/10/2021	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional marketing authorisation for Spikevax, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion. Please refer to Scientific Discussion

					'Spikevax/H/C/005791/R/25'
IB/0033/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	17/09/2021	n/a		
IB/0030/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation A.7 - Administrative change - Deletion of manufacturing sites	30/08/2021	n/a		
II/0029/G	This was an application for a group of variations. B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch	23/08/2021	04/10/2021	Annex II	The Annex IIA has been updated as follows: The time-limited exemption allowing reliance on batch control testing conducted in the registered site(s) that are located in a third country is extended from 31 July 2021 to 31 July 2022.

	control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				

IB/0020/G	This was an application for a group of variations. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	03/08/2021	n/a		
II/0026/G	This was an application for a group of variations. B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS	30/07/2021	n/a		
II/0021	Extension of indication to include use in adolescents from 12 to 17 years of age for Spikevax; as a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC and Annex II.E are updated. The Package Leaflet is updated in accordance. C.I.6.a - Change(s) to therapeutic indication(s) -	23/07/2021	23/07/2021	SmPC, Annex II and PL	Please refer to Scientific Discussion `EMEA/H/C/005791/II/0021`

	Addition of a new therapeutic indication or modification of an approved one				
IAIN/0027	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/07/2021	13/07/2021	SmPC and PL	To update sections 4.4 and 4.8 of the SmPC and sections 2 and 4 of the PL to implement the signal recommendations from the PRAC Signal assessment report on myocarditis and pericarditis with Spikevax (EPITT no 19713) adopted at the 08 July 2021 PRAC meeting.
IA/0019	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	22/06/2021	13/07/2021	SmPC, Annex II, Labelling and PL	To update the invented name of the vaccine from COVID-19 Vaccine Moderna to Spikevax.
IB/0017	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/06/2021	13/07/2021	Annex II	Update of Annex II of the product information to extend the due date for SOB3.
IB/0023/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.II.c.2.z - Change in test procedure for an excipient - Other variation	18/06/2021	n/a		
II/0018/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a	11/06/2021	13/07/2021	Annex II	The SmPC section 6.1 and Annex II.A has been updated as follows: 6.1. List of excipients Lipid SM-102 (heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate) Annex II.A. Name and address of the manufacturer

	biol/immunol method B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				responsible for batch release Recipharm Monts 18 Rue de Montbazon Monts, France 37260 In view of the declared Public Health Emergency of International Concern and in order to ensure early supply this medicinal product is subject to a time-limited exemption allowing reliance on batch control testing conducted in the registered site(s) that are located in a third country. This exemption ceases to be valid on 31 July 2021. Implementation of EU based batch control arrangements, including the necessary variations to the terms of the marketing authorisation, has to be completed by 31 July 2021 at the latest, in line with the agreed plan for this transfer of testing. The PL have been updated accordingly.

	B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes				
II/0016/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of	04/06/2021	13/07/2021	Annex II	

	specification limits A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol				

	B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch				

	control/testing takes place and any of the test method at the site is a biol/immunol method B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The				

	change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product				
II/0013/G	This was an application for a group of variations. 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) 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 B.II.f.z - Stability of FP - Other variation	25/05/2021	13/07/2021	SmPC and PL	
IB/0014/G	This was an application for a group of variations. B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation A.7 - Administrative change - Deletion of manufacturing sites	20/05/2021	n/a		
IB/0012	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	12/05/2021	13/07/2021	Annex II	Annex II of the product information is updated to extend the due date for SO2.
IB/0005	C.I.11.z - Introduction of, or change(s) to, the	11/05/2021	n/a		

	obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IB/0010/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	03/05/2021	n/a		
IB/0009/G	This was an application for a group of variations. B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	03/05/2021	n/a		
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2021	13/07/2021	PL	
II/0011/G	This was an application for a group of variations. B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.z - Quality change - Finished product - Other variation	22/04/2021	n/a		

IB/0008	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	20/04/2021	n/a		
IB/0002	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	12/04/2021	13/07/2021	Annex II	Annex II of the product information is updated to extend the due date of SOB1
II/0004/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch	09/04/2021	n/a		

	control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				
II/0007/G	This was an application for a group of variations. B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS B.II.b.4.c - Change in the batch size (including batch size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study	18/03/2021	13/07/2021	Annex II	The SmPC Annex II.A has been updated as follows: Name and address of the manufacturer of the biological active substance LONZA AG Lonzastrasse 2 Visp 3930 Switzerland LONZA AG Ibex Solutions Rottenstrasse 6 Visp 3930 Switzerland

	B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs				
IB/0003	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	23/02/2021	n/a		
II/0001	B.II.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product	15/02/2021	n/a		