



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

mRESVIA

Procedural steps taken and scientific information after the authorisation*

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

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
Variation type IB /	C.I.11 Introduction of, or change(s) to, the	26/11/2025	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).



EMA/VR/0000310233	<p>obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Other RMP changes (e.g. agreed wording + template change) - Accepted</p> <p>C.I.11.z - to update the RMP to address commitment from procedure EMA/VR/0000263124 to provide a consolidated version of the RMP following adoption of procedures EMA/VR/0000248175, EMA/VR/0000263124 and EMA/VR/0000279540. Additionally completed study P101 is being removed upon finalization of procedure EMA/VR/0000288152.</p>				
Variation type IA_IN / EMA/VR/0000304596	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.a Implementation of wording agreed by the competent authority - Refused	30/10/2025	N/A		
Variation type II / EMA/VR/0000288152	<p>C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted</p> <p>Submission of the final report from study mRNA-1345-P101 listed as category 3 study</p>	09/10/2025	N/A		The applicant submitted final results from Study mRNA-1345-P101, highlighting data from adults aged 65-79 years and women of childbearing potential (WOCBP). In adults, a single 50 µg dose elicited strong neutralising antibody responses, though durability was limited; revaccination at 12 and 24 months improved persistence. In WOCBP, a single dose induced robust responses that declined

	<p>in the RMP. This is a Phase 1, randomized, observer-blind, placebo-controlled, dose escalation study to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1345, an mRNA vaccine targeting respiratory syncytial virus (RSV), in Healthy Younger Adults Aged 18 to 49 Years, Women of Child-Bearing Potential Aged 18 to 40 Years, Healthy Older Adults Aged 65 to 79 Years, Japanese Older Adults Aged ≥60 Years, and RSV-Seropositive Children Aged 12 to 59 Months.</p>				<p>by Month 6 but remained above baseline. Safety was consistent and acceptable across groups, with no changes proposed to the SmPC which is acceptable to the Committee.</p>
<p>Variation type II / EMA/VR/0000263124</p>	<p>This was an application for a group of variations.</p> <p>C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted</p> <p>C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted</p> <p>C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the</p>	<p>02/10/2025</p>		<p>SmPC and PL</p>	

Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted

A grouped application consisting of three Type II variations, as follows: C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information of co-administration of mRESVIA (mRNA-1345) dispersion for injection, in its all-registered presentations, with a Standard dose, Seasonal Influenza Vaccine, based on data forthcoming from mRNA-1345-P302 part A clinical study. It is a Phase 3 study to evaluate safety and immunogenicity of mRNA-1345 for RSV when given alone or co-administered with a Seasonal Influenza vaccine or COVID-19 vaccine. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted. C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information of co-administration of mRESVIA (mRNA-1345) dispersion for injection, in its all-registered presentations, with COVID-19 Vaccine, based on data forthcoming from mRNA-1345-P302 part B clinical study. It is a Phase 3 study to evaluate safety and immunogenicity of mRNA-1345 for RSV when given alone or co-administered with a Seasonal Influenza vaccine or COVID-19

	<p>vaccine. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted. C.I.4: Update of section 4.5 of the SmPC in order to add drug-drug interaction information of co-administration of mRESVIA (mRNA 1345) dispersion for injection, in its all-registered presentations, with a High-dose, Quadrivalent Seasonal Influenza vaccine in Adults ≥ 65 Years of Age, based on data forthcoming from mRNA-1345-P304 clinical study. It is a Phase 3 Study to evaluate the safety and immune response of mRNA-1345, when co-administered with a High-dose, Quadrivalent Seasonal Influenza vaccine. The package leaflet is updated accordingly. The RMP version 2.0 has also been submitted.</p>				
<p>Variation type IB / EMA/VR/0000279540</p>	<p>C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II - Accepted</p> <p>To extend the due date in the RMP from Study mRNA-1345-P302 from November 2025 to March 2026 and to remove the provision of the interim results from studies P301 Part B and P302 Part C as the final study will be provided in March 2026.</p>	<p>25/07/2025</p>	<p>N/A</p>		

Variation type II / EMA/VR/0000248175	<p>C.I.6 Change(s) to therapeutic indication(s) - C.I.6.a Addition of a new therapeutic indication or modification of an approved one - Accepted</p> <p>To modify the approved therapeutic indication to include active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV for mRESVIA, based on results from Study mRNA-1345-P303 (Part A) - A Phase 3 Study to Evaluate the Immunogenicity and Safety of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus, in High-risk Adults. As a consequence, sections 4.1, 4.6, 4.8 and 5.1 of the SmPC and the corresponding sections of the Package Leaflet are updated accordingly. The updated RMP Version 1.0 has also been submitted. In addition, the MAH took the opportunity to implement editorial changes to the PI. As part of the application, the MAH also requests an extension of the market protection by one additional year.</p>	24/07/2025	15/09/2025	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000255003	<p>This was an application for a group of variations.</p> <p>B.II.e.6 Change in any part of the (primary)</p>	15/04/2025	15/09/2025	SmPC, Labelling and PL	

	<p>packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.z Other changes - Accepted</p> <p>B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.z Other changes - Accepted</p>				
Variation type IA / EMA/VR/0000256756	<p>This was an application for a group of variations.</p> <p>B.II.e.6 Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used)) - B.II.e.6.b Change that does not affect the product information - Accepted</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted</p> <p>B.I.b.2 Change in test procedure for active</p>	05/03/2025	N/A		

	<p>substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted</p> <p>B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted</p>				
Variation type IB / EMA/VR/0000245390	<p>This was an application for a group of variations.</p> <p>B.II. FINISHED PRODUCT - B.II.z Other variation - Accepted</p> <p>B.II.c.1 Change in the specification parameters and/or limits of an excipient - B.II.c.1.z Other changes - Accepted</p> <p>B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted</p> <p>A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product,</p>	13/02/2025	N/A		

	<p>packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted</p> <p>A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted</p>				
PSUR / EMA/PSUR/0000257880	- -				Maintenance