EMA/125048/2021

COMIRNATY

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/0010/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.a - Change in synthesis or recovery of a non-	22/02/2021	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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	pharmacopoeial or novel excipient - Minor change B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure				
II/0009	Type II B.II.f.1.c): To update the storage conditions of the medicinal product with additional information related to the transportation of diluted and undiluted product at non-frozen storage conditions.	19/02/2021	23/02/2021	SmPC, Labelling and PL	The SmPC sections 6.3 and 6.6 have been updated to include information related to the transportation of diluted and undiluted product at non-frozen storage conditions and to the handling of temperature excursions once removed from the freezer as follows: Unopened vial; Once removed from the freezer, the unopened vaccine can be stored for up to 5 days at 2 °C to 8 °C. Within the 5 days shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30 °C. Diluted medicinal product; Chemical and physical in-use stability, including during transportation, has been demonstrated for 6 hours at 2 ºC to 30 ºC after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. Handling of temperature excursions once removed from the freezer Stability data indicate that the unopened vial is stable for up to:

					• 24 hours when stored at temperatures from -3 °C to 2 °C • a total of 4 hours when stored at temperatures from 8 °C to 30 °C; this includes the 2 hours at up to 30 °C detailed above This information is intended to guide healthcare professionals only in case of temporary temperature excursion. The PL has been updated accordingly.
II/0008/G	This was an application for a group of variations. 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.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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change	16/02/2021	n/a		

	in the manufacturing process 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.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation 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.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.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.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.c.z - Change in control of excipients in the Finished Product - Other variation				

II/0005	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	10/02/2021	n/a		
II/0004	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	04/02/2021	n/a		
IB/0007	To update the dose interval for Comirnaty in sections 4.2, 5.1 of the SmPC and section 3 and section "The following information is intended for healthcare professionals only" of the PL to implement the recommendation of the CHMP. The wording of the dose interval in section 4.2 has been updated with a view to reflect better in section 4.2 the evidence from the submitted data and provide more clear guidance as well as to describe further in section 5.1 the available data underlying this revision. The MAH has also taken the opportunity to introduce a few editorial changes and to provide updated material affected by the change including 'How to prepare and administer poster' and 'Vaccine traceability card' In addition, the company has informed us that they updated the 'Administration video' and the 'Comirnaty website'. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/01/2021	02/02/2021	SmPC and PL	
IB/0006	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	28/01/2021	n/a		

II/0003/G	This was an application for a group of variations. B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.z - Change in control of excipients in the Finished Product - Other variation 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.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation	27/01/2021	n/a		
IB/0001	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time	26/01/2021	n/a		

	data				
II/0002/G	This was an application for a group of variations. Grouped variation: 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.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter 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.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter 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.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	08/01/2021	08/01/2021	SmPC, Labelling and PL	The change in pack size and change in specifications were approved. The SmPC sections 2, 4.2, 6.5 6.6 has been updated to reflect the following: One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution. In order to extract six doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be enough of the vaccine to extract a sixth dose from a vial. If the amount of vaccine remaining in the vial after the fifth dose cannot provide a full dose (0.3 ml), the healthcare professional must discard the vial and its contents. There should be no pooling from multiple vials to make up a full dose, and any unused vaccine should be discarded 6 hours after dilution. The Labelling and PL have been updated accordingly.

	biological/immunological medicinal products				