Comirnaty 30 micrograms/dose concentrate for dispersion for injection

Comirnaty 30 micrograms/dose dispersion for injection

Comirnaty 10 micrograms/dose concentrate for dispersion for injection

Conditional Marketing Authorisation

SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation the Marketing Authorisation Holder (MAH) shall complete, within the stated timeframe, the following measures:

Description	**Due date**
In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0315.	July 2021. Interim reports: January 2021, April 2021
In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0159.	July 2021. Interim reports: January 2021, April 2021
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001.	December 2023
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591007.	July 2024
In order to confirm the safety of Comirnaty in individuals aged 5-11 years of age, the MAH should submit 6-month safety follow-up data in subjects aged 5-11 years from study C4591007.	July 2022