COVID-19 Vaccine AstraZeneca
Conditional Marketing Authorisation

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

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

Description	Due date
In order to confirm the consistency of the active substance and finished product manufacturing process, the MAH should provide additional validation and comparability data and introduce enhanced testing.	31 December 2021 with interim updates beginning July 2021
In order to ensure consistent product quality, the MAH should provide additional information on stability of the active substance and finished product (through the scheduled duration of 12 months) and review the finished product specifications following further manufacturing experience, where applicable.	30 June 2022 with interim updates beginning July 2021
In order to confirm the efficacy and safety of COVID 19 Vaccine AstraZeneca, the MAH should submit the final Clinical Study Reports following all subjects for 1 year post second dose for the randomised, controlled, COV001, COV002, COV003 and COV005.	30 September 2022
In order to confirm the efficacy and safety of COVID 19 Vaccine AstraZeneca, the MAH should provide the final analysis from the pooled pivotal studies.	30 September 2022
In order to confirm the efficacy and safety of COVID 19 Vaccine AstraZeneca in the elderly and subjects with underlying disease, the MAH should submit the final clinical study report for study D8110C00001.	31 March 2024

II. OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES

The Marketing Authorisation Holder shall complete, within the stated timeframe, the below measures:

Description	Due date
In order to elucidate the possible mechanisms of platelet activation after vaccination and to identify the possible triggers, the MAH should conduct and submit the final report for a non-clinical study to test in-vitro expression of the S protein of COVID 19 Vaccine AstraZeneca.	31 July 2021
In order to ensure that all reported thrombotic events with thrombocytopenia and/or bleeding events are investigated by performing an in-depth exploration of platelet function in the interventional study in immunocompromised subjects, the MAH should submit the clinical study report, in accordance with a revised and agreed study protocol.	30 November 2023
In order to further characterise the thrombosis and thrombocytopenia syndrome associated to the vaccine and elucidate its mechanism, the MAH should conduct suitable clinical studies.	30 June 2024 with annual updates

Submission of a plan and timelines Submission of protocols	31 August 2021 30 September 2021
In order to evaluate antibody persistence, the Applicant should submit 6-month immunogenicity data of the COV trials. Published data Follow-up with validated data	 31 July 2021 31 January 2022
In order to investigate potential correlate(s) of protection, the Applicant should provide data on breakthrough cases. Published data Detailed analyses on breakthrough cases and validated data on correlates of protection	 31 July 2021 31 January 2022
In order to further evaluate vaccine efficacy against transmission, the Applicant should provide updated data from the COV002 study.	31 January 2022