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 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.	28 February 2023
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.	31 December 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.	31 December 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 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
In order to investigate potential correlate(s) of protection, the Applicant should provide data on breakthrough cases.	31 December 2022