

VAXZEVRIA
COVID-19 Vaccine
Full Marketing Authorisation

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 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 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