Annex IV

Conditions to the marketing authorisation(s)

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The marketing authorisation holders shall complete the below condition, within the stated timeframe, and competent authorities shall ensure that the following is fulfilled:

Each MAH shall conduct and submit for their medicinal product(s) the results of placebo-controlled, double-blind multicentre RCT(s) according to agreed protocols in order to further characterise the efficacy and safety, of their bacterial lysate based product(s) in their authorised indication(s). The study population should be representative for the authorised indication(s). The protocols should be agreed with the relevant NCAs.	
The clinical study report should be submitted to the relevant National Competent Authorities by:	31 March 2026