Annex IV

Conditions to the marketing authorisation(s)

Conditions to the marketing authorisation(s)

Conditions Symbioflor 2 (*Escherichia coli* bacteria (cells and autolysate)) and associated names	**Date**
In order to address the uncertainties with regards to the efficacy and safety of Symbioflor 2 (*Escherichia coli* bacteria (cells and autolysate)) and associated names in the treatment of irritable bowel syndrome in adult patients, the MAH should conduct and submit the results of a well-designed and adequately powered multi-centre double blind randomised placebo controlled post approval efficacy study allowing for relevant subpopulation analyses, in accordance with an agreed protocol to assess the efficacy of Symbioflor 2 in the treatment of IBS in general versus subtypes of the disease such as IBS C and IBS D, both gender, disease severity and address the sustainability of efficacy The final study report should be submitted to the relevant National Competent Authorities.	Submission of the final study results by March 2022.