Annex IV

Conditions for lifting the suspension

Only applicable to products containing a polymethacrylate-triethylcitrate coating as modified-release mechanism

For the suspension to be lifted the Marketing Authorisation Holders would need to provide the National Competent Authorities with the following:

Evidence that the product has been reformulated, that it exhibits an acceptable release profile with the same quality, safety and efficacy profile of the currently authorised formulation but without the clinically significant interaction with alcohol. The new formulation must be approved by the National Competent Authorities of the concerned Member States.