Medicines & Healthcare products Regulatory Agency

MHRA

Variation Type	Positive EMA approval or CHMP Opinion Stage, as appropriate, before exit day	MHRA assessment	Fee payable	Include in Initiating Sequence
Type IA: (i) Submitted to EMA before 1 January 2021 and not rejected or, (ii) submitted to EMA on or after 1 January 2021 and not rejected before data submission date	N/A	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)
Type IB: Submitted to EMA but not granted before 1 January 2021	Yes	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)

Type IB: Submitted to EMA but not granted before 1 January 2021	No	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)
Type II: Submitted to EMA but not granted before 1 January 2021	Yes	No	No	Yes, (and list in summary of historical regulatory activity accompanying Initiating Sequence)
Type II in clock stop: Submitted to EMA but not granted before 1 January 2021, And in clock stop	No	Yes, assessment of replies (*)	No	No: Separate Submission needed along with or after Initiating Sequence (either minimal or complete)
Type II : Submitted to EMA but not granted before 1 January 2021, procedure clock on, after first clock off	No	No	No	No: Separate Submission needed along with or after Initiating Sequence (either minimal or complete)

Type II Submitted to EMA but not granted before 1 January 2021, And before procedure first clock stop	No	Yes (*)	Yes	No: Separate Submission needed along with or after Initiating Sequence (either minimal or complete)
Type IA variations: Submitted to EMA after Initiating Sequence	N/A	Yes	No	Separate Submission needed after Initiating Sequence (either minimal or complete)
Type IB/II variations: Submitted to EMA on or after 1 January 2021	N/A	Yes (**)	Yes	No: Separate Submission needed along with or after Initiating Sequence (either minimal or complete)
Type IB/II variations: Submitted to EMA after initiating sequence	N/A	Yes (**)	Yes	N/A: Separate Submission needed

(* - If the MAH wishes for the variation to be put on hold pending finalisation by the EMA, so that the variation can be processed under the recognition route and where a lower fee is chargeable, please advise the MHRA at the time of initial submission or where relevant the submission of the responses.)

(** - If the identical changes have already been approved for the corresponding centralised product and provided evidence of this is included as part of the submission to the MHRA, the variations will be processed under the recognition route.)