

Table 1 – Summary of approach to Variations

Variation	Positive CHMP Opinion Stage before exit day	MHRA Assessment	Fee Payable	Include in Initiating Sequence
Type IA (i) Submitted to EMA before exit day and not rejected or (ii) submitted to EMA after exit day 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 exit day	Yes			
Type IB Submitted to EMA but not granted before exit day	No			
Type II Submitted to EMA but not granted before exit day	Yes			
Type II in clock stop Submitted to EMA but not granted before exit day 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 before clock stop Submitted to EMA but not granted before exit day. And before procedure first clock stop	No	Yes	Yes	
Type IB/II variations Submitted to EMA after exit day	N/A			