		IRP Lifecycle Validation Checklist: Variation, Renewal etc (Version 1.3)	
1		Applicant's reference (If available)	
2		This International Recognition application concerns	Select an item
3	**a**	Specify the Reference Regulator (RR)	Select an item
	b	If the response to (3a) above is EU Member State, specify the country	Select an item
4		Specify the route used to obtain the Initial UK/GB application	Select an item
5	**a**	When was the procedure that this application is reliant on approved by the Reference regulator	
	b	A declaration that the UK IRP application is for the same product as that approved by the RR is included. The same product means the same qualitative and quantitative composition, same dosage form, same MAH (or company group or 'licencees')	Select an item
	c	A declaration that all iterations of the Reference Regulator assessment reports is included in the dossier	Select an item
	d	All the assessment reports included are listed in Annex I below	Select an item
6	**a**	Are there any conditions associated with the RR approval	Select an item
	b	If the response to (6a) is Yes details are included in a separate document called m1/eu/10-cover/cc/RR-conditions-VAR.EXT	Select an item
7	**a**	Are there any proposed conditions for UK/GB approval:	Select an item
	b	If the response to (7a) is Yes details are included in a separate document called m1/eu/10-cover/cc/RR-conditions-VAR.EXT	Select an item
8	**a**	For Variations, is a new indication being added:	Select an item
	b	Are there differences in the wording of the proposed therapeutic indications for UK/GB and the therapeutic indications approved by the RR	Select an item
	c	If the response to (8b) is Yes, justification for these changes is provided in m1/eu/10-cover/cc/RR-justification-UK-GB-indications-VAR.EXT	Select an item
9	**a**	For Variations, does the variation impact an ASMF	Select an item
	b	A declaration from the applicant that the ASMF Holder has submitted the Applicant's and Restricted Parts of the ASMF, including approved variations and all iterations of the assessment reports on the Applicant's and Restricted Parts, is included in the dossier	Select an item

	c	A letter for permission of access is included in the dossier	Select an item
10	**a**	Where relevant, are there any differences in the proposed UK RMP compared to the RMP that was approved by the RR	Select an item
	b	Where there are differences in the proposed safety concerns, additional pharmacovigilance activities or additional risk minimisation measures, brief details are provided in Annex II below	Select an item
	c	Is the GB/UK specific Annex (Guidance on pharmacovigilance procedures) used and included with the RMP in 1.8.2	Select an item
11	**a**	For this variation (or renewal) application, has the same change been approved, withdrawn, refused, or rejected by any other RR? Select all that applies	☐ Approved ☐ Withdrawn ☐ Refused ☐ Rejected
	b	Reasons for any withdrawal, refusal or rejection is provided in Annex III below	Select an item
12		If the variation application affects the SmPC, labelling and/or package leaflet. Clean and tracked versions has been enclosed as word files in the working documents. All changes in the text, in comparison with the previously approved version of product information, has been marked with track-changes in the highlighted versions	Select an item
		Annex I (5d) – List Assessment reports provided.	
		Annex II (10b) – Differences in RMP	
		Annex III (11b) – Reasons for withdrawal, refusal or rejection	