Appendix I

CHECKLIST FOR NEW/ADDITIONAL INDICATION (AI Reliance - to be filled by the applicant

PRODUCT NAME :
REGISTRATION NO. (MAL) :
PRODUCT REGISTRATION HOLDER (PRH) :
CHOSEN REFERENCE AGENCY :

ADDITIONAL INDICATION	**MALAYSIA**	**CHOSEN REFERENCE AGENCY**	**COMMENTS**
Proposed Indication			
Proposed Posology			

APPROVAL BY OTHER REFERENCE AGENCIES			
Reference agency	**Date of AI approval**	**Approved Indication / Posology (specific to new indication only)**	**Comment**
EMA			
US FDA			
UK MHRA			
TGA Australia			
PMDA Japan			
Health Canada			
ANSM France			
Swedish Medical Products Agency			
Swissmedic			

** In the event that the chosen reference drug regulatory agency does not bear the most stringent indication(s), dosing regimen(s), patient group(s) and/or direction(s) of use among those approved by the reference drug regulatory agencies, **clinical justifications** are to be provided upon submission.*

DOCUMENTS SUBMITTED	**Yes/ No**	**COMMENT**
- complete clinical assessment reports (unredacted/unedited)		
- question and answer documents between the applicant and agency and all annexes		
- declaration statement to indicate that the assessment report, list of Q & A and all other relevant documents provided are authentic		
- Other supporting document/clinical guidelines (to support the new indication) – *if any*		

CLINICAL STUDIES SUBMITTED			
Clinical study (s)	**Malaysia**	**Chosen reference agency**	**Comments**
Clinical Study 1	− Study name		
	− Study design − Primary objective − Primary endpoints		
	Results (brief)		
	Clinical efficacy & safety conclusion		

Clinical Study 2 (*if any)*	– Study name		
	– Study design – Primary Objective – Primary endpoints		
	Results (brief)		
	Clinical efficacy/ safety conclusion		
PACKAGE INSERT (SUMMARY OF CHANGES) *summary of other changes must be those consequential to the Additional Indication (e.g., Summary of other changes resulting from the new indication and posology)*			
Section	**Malaysia**	**Chosen reference agency**	**Comments**