Type IA & IB/II Presubmission Checklist

TECHNICAL SUBMISSION REQUIREMENTS	Tick
Dossier is submitted through CESP or MHRA Portal. The application follows the guideline on e-submission.	
COVER LETTER	
Present, dated and signed by authorised contact person.	
Refers to the same medicinal product(s), MRP/EU numbers and procedure as listed in the application form. DDL section completed (if applicable)	
APPLICATION FORM	
States the correct name and contact details of the applicant/MA holder and of the contact person.	
National Authorisation in MRP / National Authorisation	
Correct box is selected	
Variation procedure number	
The variation procedure number is indicated (if applicable)	
Type of application	
Correctly identified by ticking the box(es) type IA or type IA_{IN} & IB/II (as applicable)	
Indicates whether the submission is single or grouped	
Products concerned by this application	
MRP and PL numbers of all affected marketing authorisations are listed	
Variations included in this application	
All changes applied for are correctly classified according to the Guideline on the details of the various categories of variation.	
If more than 1 change falls under the same change code the scope should be repeated for each specific change.	
Variation(s) affecting more than one marketing authorisation/PL	
Same (group of) variation(s) applies to all marketing authorisations/PL.	
All marketing authorisations/PL belong to the same marketing authorisation holder.	
The main signatory confirms authorisation to sign on behalf of the designated contacts.	
Date of implementation (refers only to IA)	
Must be within the last 12 months. For IA_{IN}, submission should be immediately after implementation.	
Scope	
Provides specific description and background of all requested change to the licence	
Present and Proposed table	
All requested changes are described *(If necessary provide this section as an Annex if very long)*	
(including for Product Information, if applicable).Dossier section number(s) is/are indicated at the lowest possible level.	
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The following amended product information proposals are provided	
Relevant boxes are ticked as appropriate (do not remove this section)	
Declaration of the applicant	
Relevant boxes are ticked as appropriate	
SUPPORTING DOCUMENTATION	
Classification Guideline	
Copy of the relevant page(s) are attached for each requested change	
All relevant check boxes are ticked. If a condition or documentation requirement is not applicable "NA" should be specified and adequate justification should be provided. Please note: Type II submissions additionally require a QOS (Expert statement – m2) and Expert CV (Clinical or pre-Clinical) -m1.4.1	
Grouping Approval	
Grouped variation should include reference to CMDh acceptable grouping or RIS approval	
Fee (refers only to IB/II)	
Appropriate fee provided	
Documentation	
All documents are supplied in correct CTD location.	
Amended section(s) of the dossier only show(s) the change(s) applied for.	
If QP declaration is required ensure that it: i) Uses the CMDh template or ensure all information requested by template is provided ii) The basis of the audit is stated (on-site/paper)	

iii) The specific sites/functions covered by the declaration are stated. iv) Job title of QP declaration should be signed by a “Qualified Person”.	
PRODUCT INFORMATION (SmPC, Labelling and Leaflets) if applicable	
Only changes declared in the Present and Proposed sections are included	
Tracked changes and clean version are provided	
Clean versions of the Labels (i.e. consolidated components of the carton and blister) and Leaflets are provided in pdf format and personal information is removed.	
Revised SmPC fragments are provided individually in word format (in “working documents”)	