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Human Medicines Division

Pre-notification check for Type IA/IA$_{IN}$ Variations

This pre-notification checklist is aimed at facilitating submission of complete and correct Type IA and Type IA$_{IN}$ variation notifications by marketing authorisation holders (MAHs).

Guidance for marketing authorisation holders

The Agency strongly recommends that this checklist is used in advance of submission of any Type IA or Type IA$_{IN}$ variation; you should be able to answer "Yes" to every item listed below unless a specific point is not applicable ("n/a") to the application in question. Please note that this checklist should not be included in the submission.

Commission Regulation (EC) No 1234/2008 ('the Variations Regulation') defines Type IA/IA$_{IN}$ variations as minor variations which have only a minimal impact, or no impact at all, on the quality, safety or efficacy of the medicinal product and do not require prior approval before implementation ("Do and tell" procedure). Type IA/IA$_{IN}$ variations are reviewed by the Agency within 30 days following receipt, without involvement of the Rapporteur or Co-Rapporteur. These are simple procedures without clock-stop and for which interactions with Applicants are not envisaged.

However, in exceptional cases, the Agency may issue a request for supplementary information. Responses should be provided within 4 working days. Failure to respond within the specified deadline may lead to an unfavourable outcome.

For variations classified as Type IA or Type IA$_{IN}$ relating to:
- changes to the Risk Management Plan (RMP)
- implementation of an outcome, such as a PRAC signal recommendation wording (when classified as Type IA$_{IN}$)
- changes to an Active Substance Master File (ASMF) an additional section of the checklist is presented addressing the specific submission requirements.

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Type IA and Type IA$_{IN}$ Pre-notification checklist

Type IA/IA$_{IN}$ submission checklist[1]	Yes	n/a
TECHNICAL SUBMISSION REQUIREMENTS		
• Dossier is submitted in eCTD format[2] and is technically valid (i.e. has passed eCTD technical validation criteria).		
COVER LETTER (optional)		
• For notifications including only Type IA or Type IAIN variations, super-groupings and annuals updates, the submission of a cover letter is not necessary. • A tracking table is required. A missing tracking table will lead to a technical invalidation.		
APPLICATION FORM[3]		
• Present, correct version, dated • **Variation procedure number(s) should be left blank,** except in case of a super-grouping where the procedure number needs to be obtained in advance via EMA service desk. • The name and address of the MAH and of the contact person are stated with the organisation details filled from SPOR OMS.		
'Type of application' • Correctly identified by ticking the box(es) Type IA and/or Type IA$_{IN}$, as applicable. • Indicates whether it is a single or a (super-) grouped submission. • Annual update tick box should be ticked, as applicable. Implementation date of the earliest Type IA/ IA$_{IN}$ will be autofilled with information from section 3 of the eAF.		
'**Products concerned by this application**' • EU marketing authorisation number(s) of (all) affected presentation(s) is/are listed.[4] • Is/are the same as that/those indicated in the Present/Proposed table, Precise Scope and cover letter.		
'**Types of change(s)**' • All changes applied for are correctly classified according to the Guideline on the details of the various categories of variations or a recommendations on unforeseen variation according to Article 5 of Commission Regulation (EC) No 1234/2008. • When two or more changes fall under the same indent, the variation classification category is indicated as many times as there are changes applied for (e.g. scope Q.II.e.6.a.1 is repeated 'x' times for 'x' additional new pack sizes; scope E.4 is repeated for each manufacturing site affected by the change). • The **date of implementation** is provided. The variation has been submitted immediately following implementation (Type IA$_{IN}$) or no earlier than 9 months and no later than 12 months after the first implementation date of the Type IA variation included in the 'Type IA annual update', as appropriate, unless one of the exemptions apply. • Relevant conditions and documentation, as specified in the Guideline on the details of the variatious categories of variations or a recommendation on an unforeseen variation according to Article 5 of Commission Regulation (EC) No 1234/2008 are ticked. In case of variation(s) affecting more than one Marketing Authorisation (-super-group): • the same (group of) variation(s) is applied for all Marketing Authorisations but the scope(s) is/are not repeated for each product[5]		

[1] Guidance for submitting Type IA variations is provided in the post-authorisation guidance 'Q&A: type IA variations'.
[2] Please refer to the "eSubmission: eCTD".
[3] As published on the Commission's website in Volume 2C of the Notice to applicants.
[4] Please avoid stating 'See Annex A' if **not** all presentations are affected by the change(s) applied for.
[5] It is understood that the same change(s) apply/ies to all products included in the application.

Type IA/IA$_{IN}$ submission checklist[1]	Yes	n/a
'Precise scope and background for change' It contains for each change applied for in the section 'Types of Change(s)': • A variation classification category and a precise description of the change[6]. If the Product Information (PI) is affected, the updated sections should also be provided here. • When two or more different changes fall under the same scope, the variation classification category is indicated as many times as there are changes (e.g. scope Q.II.e.6.a.1 is indicated for each additional new pack size). • A justification is provided for Type IA notification submitted outside an annual update with reference to the exemption applied for[7]. • Additional background information should be included as applicable as a separate paragraph.		
'Present and Proposed' table (or provided as an attachment) • Reflects all the changes applied for in the section 'Types of Change(s)'. • For clarity, the present and proposed wording is, for each scope, presented under the relevant variation classification category. • Shows the precise present and proposed wording as in the relevant sections of the dossier and, if applicable, in the PI. For further guidance see footnotes 9 and 10[8] of the Application Form (identifies the changes with the appropriate highlights). • Dossier section number(s) is/are indicated at the lowest possible level. • When changes result in any updates of manufacturing sites (i.e. name/address change, addition or replacement of manufacturing site(s) or the Marketing Authorisation Holder) the present/proposed table is completed by selecting the organisation from SPOR/OMS to autofill address details. • All editorial changes are included and a justification as to why they are considered editorial is included in the application.		
'Annexed documents (where appropriate)' • Relevant boxes are selected or left un-ticked as appropriate. If changes to the Annex II of the PI are proposed, the box "Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation" should be ticked.		
'**Declaration of the Applicant**' Boxes relating to: • "There are no other changes than those identified in this application […]". • "Where applicable, all conditions as set for the variation(s) concerned are fulfilled". • "For Type IA notifications: the required documents as specified for the changes concerned have been submitted". are ticked. In case of variation(s) affecting more than one Marketing Authorisation (super-group), ensure that all Marketing Authorisations belong to the same marketing authorisation holder[9] and that the following boxes: • […] the MAs concerned belong to the same MAH (under 'Declaration of the Applicant'). • […] the main signatory confirms authorisation to sign on behalf of the designated contacts […] (under 'Signature'). are also ticked.		

[6] A 'Guidance for applicants for the preparation of the 'precise scope' section of the variation application form' has been prepared to support marketing authorisation holders in completing this section.
[7] Please refer to "European Medicines Agency post-authorisation procedural advice for users of the centralised procedure".
[8] As stated in the eAF "For SPC, labelling and package leaflet changes, underline or highlight the changed words presented in the table above or provide as a separate Annex".
[9] As per Commission Communication 98/C 229/03 'applicants belonging to the same mother company or group of companies and applicants having concluded agreements or exercising concerted practices concerning the placing on the market of the relevant medicinal product have to be taken as one entity'.

Type IA/IA$_{IN}$ submission checklist[1]	Yes	n/a
SUPPORTING DOCUMENTATION		
Relevant documentation listed in Annex IV of the Variations Regulation and in the Commission Classification Guideline is provided. • Included and presented in accordance with the appropriate EU-CTD format headings and numbering. • Is complete, updated, and correctly reflects the changes listed in the Present and Proposed table. • Affected section(s) of the dossier correctly show(s) the change(s) applied for.		
PRODUCT INFORMATION (SMPC (ANNEX I), ANNEX II, LABELLING (ANNEX IIIA), PL (ANNEX IIIB) AND ANNEX A		
• The PI includes only changes declared in the Present and Proposed table in the Application Form. • The PI is provided in all EEA languages in Word format (with tracked changes in anonymised format, including the required headers[10]) and as clean PDFs correctly formatted[11] and named (accordingly to the formatting checklist[12]). No other versions or formats are included. • The PI correctly reflects the scope of the variation and is based on the latest approved version. • Annex A[13] is provided in all EEA languages in Word format (with tracked changes) and as clean PDF when its content is modified by a change (e.g. addition or deletion of a presentation, change in product name). • The formatting checklist for minor procedures without linguistic review[12] has been completed and included in the submission.		
New EU number(s) • Reserved with the EMA[14]. • Correctly inserted in Annex A and in the Product Information.		

Additional checklists addressing specific submission requirements for changes to RMP, implementation of recommendations (PRAC) and changes to ASMF

Type IA/IA$_{IN}$ submission checklist[1]	Yes	n/a
CHANGES TO THE RMP		
• The version number is correctly reflected.		
• The changes to the RMP should be included in the Application Form in the 'Present and Proposed' table or provided as a separate Annex. Changes to RMP as part of Type IA variations need to include the **exact** wording as agreed within the context of a previous regulatory procedure. • **RMP,** based on the latest approved version, only including the changes covered by the scope of the variation **with tracked changes or** • RMP including a summary of changes from the previous RMP version (mandatory in case of an update to the latest RMP template). • The redacted RMP (clean and tracked) and the signed RMP Publication Declaration[15], ensuring personal data and commercial confidential information[16] are removed, is provided**.**		
IMPLEMENTATION OF OUTCOME – C.3 SCOPE -		
• Application Form listing reference to the recommendation of the competent authorities. • For PRAC signal recommendation: the EPITT number (EPITT no{number}) is included. The agreed wording is correctly reflected in all applicable sections of the SmPC and PIL as published		

[10] Please refer to the "Statement to be included in the tracked changed product information annexes when submitting the final translations to the Agency".
[11] Please refer to the "User guide on how to generate PDF versions of the Product Information and other annexes - human"
[12] Checklist for the submission of product information annexes and Annex A for minor procedures without linguistic review".
[13] Please refer to the "Annexe A QRD Template".
[14] New EU sub-numbers for Type IA variations concerning an additional presentation (e.g. new pack size) should be requested to the European Medicines Agency prior to the submission of the procedure. Please refer to Q.11 of the published post-authorisation guidance "Q&A: Type IA variations".
[15] Please refer to question 16.14 of "EMA's post-authorisation procedural advice for users of the centralised procedure".
[16] Please refer to the "Guidance on the anonymisation of protected personal data and assessment of commercially confidential information during the preparation and redaction of risk management plans".

Type IA/IA$_{IN}$ submission checklist[1]	Yes	n/a
on the EMA website[17].		
• Annexes provided in Word format (with tracked changes) and as clean PDF correctly formatted[11]. No other versions or formats are included.		
CHANGES TO AN ASMF		
The MAH should submit: • Application Form listing the **ASMF number {EMEA/ASMF/xxxxx or EU/ASMF/xxxxx**} in the **'Present and Proposed' table (last row).** In order to avoid comments, the EMA strongly recommends the submission of the variation application once the ASMF holder successfully carried out the submission of relevant sections of the ASMF in the appropriate eCTD format. • Revised sections of the dossier (Applicant's Part), which should correspond to the ASMF Holder's Applicant's Part.		
The MAH should liaise with the ASMF Holder to ensure that the following documentation is submitted: • Submission letter and administrative details (Annex 3 of the ASMF Guideline)[18, 19]. • Detailed table of changes, clearly showing the present and proposed situation. Dossier section number(s) is/are indicated at the lowest possible level. • Revised sections of the ASMF dossier (Applicant's/Restricted Part) reflecting changes to the previously accepted version, as applicable.		

This checklist is published for transparency purposes and does not preclude that during the actual review of the submitted application the Agency may identify other issues that could impact the outcome.

[17] Please refer to "PRAC recommendations on safety signals".
[18] Please refer to "Guideline on Active Substance Master File Procedure".
[19] Please refer to "Additional guidance on documents relating to an active substance master file".