EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2021
EMA/764767/2014 Rev. 2
Veterinary Medicines Division

Pre-notification check for type IA/IA$_{IN}$ variations

Ensuring the quality of veterinary type IA/IA$_{IN}$ variation submissions

Background

Type IA and IA$_{IN}$ (type IA immediate notification) variations are minor variations which have only a minor impact, or no impact at all, on the quality, safety or efficacy of the medicinal product and which do not require prior approval before implementation ("Do and tell" procedure). Type IA and 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 interaction with the applicant is not envisaged. However, in exceptional cases, the Agency may issue a Request for Supplementary Information, in response to which the missing information should be provided within 4 working days. Failure to respond within 4 working days will lead to rejection of the variation and the consequent need to submit a new application.

In order to minimise the chance of applicants failing to submit all of the required information, the Agency has prepared the attached pre-notification checklist. The intention is to help marketing authorisation holders to submit complete and correct type IA and type IA$_{IN}$ variation notifications.

Instructions 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 in the checklist unless it is not applicable "n/a" with respect to the particular application in question.

Please also refer to the notification published on the Agency website related to changes in fee processing for type IA variations as of 1 January 2015, whereby fees will still apply to notifications that are rejected.

Procedural announcement of 12 September 2014

Please note that this checklist is intended as an administrative 'aide memoir' for the applicant and should not be included in the submission.

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

Type IA/IA$_{IN}$ submission checklist[1]	Yes	n/a
TECHNICAL SUBMISSION REQUIREMENTS		
▪ Dossier is submitted through eSubmission Gateway/Web Client. The application follows the guideline on e-submission[2] and VNeeS report is attached in the dossier.	☐	
COVER LETTER		
▪ Present, dated and signed by authorised contact person. ▪ Refers to the same medicinal product(s), EU numbers and procedure as listed in the application form (eAF). ▪ Letter of authorisation is provided if the application is not submitted by the authorised contact person. ▪ Where applicable, previous regulatory or procedural advice requested from the Agency is attached.	☐ ☐ ☐ ☐	
APPLICATION FORM (EAF)[3]		
▪ Dated and signed by the contact person specified in section 2.4.3 in Part 1A of the application form for the initial application or a letter of authorisation is attached. ▪ States the correct name and contact details of the applicant/MA holder and of the contact person.	☐ ☐	
'Variation procedure number' ▪ The variation procedure number is indicated (confirm with Agency in case of doubt).	☐	
'Type of application' ▪ Correctly identified by ticking the box(es) type IA or type IA$_{IN}$ (or both, if applicable). ▪ Indicates whether it is a single or a grouped submission.	☐ ☐	
'**Products concerned by this application**' ▪ EU marketing authorisation numbers of all affected presentations are listed. ▪ Are the same as those indicated in the Present and Proposed table, Precise Scope and cover letter.	☐ ☐	
'**Variations included in this application**' ▪ All changes applied for are correctly classified according to the Guideline on the details of the various categories of variations (2013/C 223/01). ▪ When two or more different changes fall under the same scope, the scope number is indicated as many times as there are changes (e.g. scope B.II.e.5.a.1 is indicated for each additional new pack size; when in doubt, confirm with EMA before submission). ▪ Relevant conditions and documentation, as specified in the Guideline[4], are ticked	☐ ☐ ☐	
Variation(s) affecting more than one marketing authorisation (IG) ▪ Same (group of) variation(s) applies to all marketing authorisations. ▪ All marketing authorisations belong to the same marketing authorisation holder[5]. ▪ The following boxes are ticked: ○ […] the MAs concerned belong to the same MAH ○ […] the main signatory confirms authorisation to sign on behalf of the designated contacts […]. The scope(s) **should not** be repeated for each product	☐ ☐ ☐ ☐	
▪ **Date of implementation** is provided. ▪ The variation has been submitted at the latest within one year (type IA) or immediately following implementation (type IA$_{IN}$), as appropriate.	☐ ☐	

[1] Guidance for submitting type IA variations is provided in the post-authorisation guidance 'Q&A: type IA variations': (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000099.jsp&mid=WC0b01ac058002d9b4)
[2] http://esubmission.ema.europa.eu/tiges/vetesub.htm
[3] As published on the Commission's website in Volume 6C of the Notice to applicants
[4] Guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (2013/C 223/01)
[5] As per Commission Communication 98/C 229/03

Type IA/IA$_{IN}$ submission checklist[1]	Yes	n/a
'Precise scope' It contains information for each change applied for in the section 'Variations included in this application': ▪ A scope number and a precise description of the change. ▪ When two or more different changes fall under the same scope, the scope number is indicated as many times as there are changes (e.g. scope B.II.e.5.a.1 is indicated for each additional new pack size; when in doubt, confirm with EMA before submission).	☐	
'Present and Proposed' table ▪ Reflects all the changes applied for in the section 'Variations included in this application'. ▪ Shows precise Present and Proposed wording as in the relevant sections of the dossier and, if applicable, in the Product Information (including editorial corrections if any). ▪ Dossier section number(s) is/are indicated at the lowest possible level. *In case this table is extensively long, it can be attached as a separate Annex in Part 1 of the dossier, but this needs to be mentioned in the 'Present and Proposed' section of the AF.*	☐ ☐ ☐	
Annex(es) related tick boxes ▪ Relevant boxes are selected or left un-ticked as appropriate, but the section is not removed.	☐	
'**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" ▪ "The required documents as specified for the changes concerned have been submitted" ▪ "This notification/application has been submitted simultaneously […] both to the Agency and rapporteur […]" are ticked.	☐ ☐ ☐ ☐	
SUPPORTING DOCUMENTATION		
Documentation listed in Annex IV of the Variations Regulation and in the Commission Classification Guideline ▪ Included and presented in accordance with the appropriate headings and numbering. ▪ Is complete, updated, and correctly reflects the changes listed in the Present and Proposed table.	☐ ☐	
Amended section(s) of the **dossier** correctly show(s) the change(s) applied for.	☐	
PRODUCT INFORMATION (SPC, ANNEX II, LABELLING, PACKAGE LEAFLET) AND ANNEX A		
▪ Annexes include only changes declared in the Present and Proposed table in the eAF. ▪ Annexes provided in Word version (with track changes) and as a clean PDF correctly formatted[6]. No other versions or formats are included. ▪ Correct latest version is provided as a full set of annexes in all EEA languages. ▪ Annex A provided in all EEA languages when its content is modified by a change (e.g. addition or deletion of a presentation).	☐ ☐ ☐ ☐	
New EU number(s) ▪ Reserved with the EMA[7]. ▪ Correctly inserted in Annex A and in the Product Information.	☐ ☐	

[6] Please refer to the "User guide on how to generate PDF versions of the Product Information" (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2011/02/WC500101956.pdf)

[7] As of 1st April 2011, new EU sub-numbers for type IA variations concerning an additional presentation (e.g. new pack size) should be requested from the European Medicines Agency similarly to the procedure already in place for obtaining new EU sub-numbers for type IB variations