



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines and Product Data Management

Pre-notification check for type IA variations: ensuring the quality of veterinary type IA variation submissions

Background

Type IA 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 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.



Type IA and IA_{IN} Pre-notification checklist

Type IA submission checklist ¹	Yes	n/a
TECHNICAL SUBMISSION REQUIREMENTS		
<ul style="list-style-type: none"> ▪ Dossier is submitted through eSubmission Gateway/Web Client. The application follows the guideline on e-submission² and VNeS report is attached in the dossier. 	<input type="checkbox"/>	
COVER LETTER		
<ul style="list-style-type: none"> ▪ Present, dated and signed by authorised contact person. ▪ Letter of authorisation is provided if the application is not submitted by the authorised contact person. ▪ Refers to the same medicinal product(s), EU numbers and procedure as listed in the application form. ▪ A formatted table related to fees is attached and fully completed.³ 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
APPLICATION FORM⁴		
<ul style="list-style-type: none"> ▪ Dated and signed by the contact person specified in section 2.4.3 in Part 1A of the initial application form or a letter of authorisation is attached. ▪ States the correct name and contact details of the applicant/MA holder and of the contact person. 	<input type="checkbox"/> <input type="checkbox"/>	
<p>'Variation procedure number'</p> <ul style="list-style-type: none"> ▪ The variation procedure number is indicated (confirm with Agency in case of doubt). 	<input type="checkbox"/>	
<p>'Type of application'</p> <ul style="list-style-type: none"> ▪ 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. 	<input type="checkbox"/> <input type="checkbox"/>	
<p>'Products concerned by this application'</p> <ul style="list-style-type: none"> ▪ EU marketing authorisation numbers of all <u>affected</u> presentations are listed. ▪ Are the same as those indicated in the Present and Proposed table, Precise Scope and cover letter. 	<input type="checkbox"/> <input type="checkbox"/>	
<p>'Variations included in this application'</p> <ul style="list-style-type: none"> ▪ <u>All changes</u> applied for are correctly classified according to the Guideline on the details of the various categories of variations (2013/C 223/01). <p><i>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).</i></p>	<input type="checkbox"/>	
<p>Variation(s) affecting more than one marketing authorisation</p> <ul style="list-style-type: none"> ▪ Same (group of) variation(s) applies to all marketing authorisations. ▪ All marketing authorisations belong to the same marketing authorisation holder⁵. ▪ The following boxes are ticked: <ul style="list-style-type: none"> ○ [...] the MAs concerned belong to the same MAH ○ [...] the main signatory confirms authorisation to sign on behalf of the designated contacts [...]. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
<ul style="list-style-type: none"> ▪ Date of implementation is provided. ▪ The variation has been submitted at the latest within 1 year (type IA) or immediately following implementation (type IA_{IN}), as appropriate. 	<input type="checkbox"/> <input type="checkbox"/>	

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 http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000188.jsp&mid=WC0b01ac058002d9ae

⁴ As published on the Commission's website in Volume 6C of the Notice to applicants

⁵ As per Commission Communication 98/C 229/03

Type IA submission checklist ¹	Yes	n/a
<p>‘Precise scope’</p> <p>It contains information for each change applied for in the section ‘Variations included in this application’:</p> <ul style="list-style-type: none"> ▪ A scope number and a precise description of the change. <p><i>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).</i></p>	<input type="checkbox"/>	
<p>‘Present and Proposed’ table</p> <ul style="list-style-type: none"> ▪ 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. <p><i>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.</i></p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
<p>Annex(es) related tick boxes</p> <ul style="list-style-type: none"> ▪ Relevant boxes are selected or left un-ticked as appropriate, but the section is not removed. 	<input type="checkbox"/>	
<p>‘Declaration of the applicant’</p> <p>Boxes relating to:</p> <ul style="list-style-type: none"> ▪ “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 [...]” <p>are ticked.</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
SUPPORTING DOCUMENTATION		
<p>Classification Guideline</p> <ul style="list-style-type: none"> ▪ Copy of the relevant page(s) from the Classification Guideline is/are attached for each change applied for. ▪ <u>Relevant</u> conditions and documentation, as specified in the Guideline⁶, are <u>ticked</u>. 	<input type="checkbox"/> <input type="checkbox"/>	
<p>Documentation listed in Annex IV of the Variations Regulation and in the Commission Classification Guideline</p> <ul style="list-style-type: none"> ▪ 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. 	<input type="checkbox"/> <input type="checkbox"/>	
Amended section(s) of the dossier correctly show(s) the change(s) applied for.	<input type="checkbox"/>	
PRODUCT INFORMATION (SPC, ANNEX II, LABELLING, PACKAGE LEAFLET) AND ANNEX A		
<ul style="list-style-type: none"> ▪ Annexes include only changes declared in the Present and Proposed table in the application form. ▪ Annexes provided in Word version (with track changes) and as a clean PDF correctly formatted⁷. 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). 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
<p>New EU number(s)</p> <ul style="list-style-type: none"> ▪ Reserved with the EMA⁸. 	<input type="checkbox"/>	

⁶ 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)

⁷ 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)

Type IA submission checklist ¹	Yes	n/a
▪ Correctly inserted in Annex A and in the Product Information.	<input type="checkbox"/>	

⁸ 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
