



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

VMD only App No:

UK ANNEX TO THE APPLICATION FORM FOR VARIATIONS TO MARKETING AUTHORISATIONS

To be completed for every variation application

Please note an incomplete form will lead to the rejection of your application at validation.

National Procedures only: please complete the following:

- | | |
|--|--|
| <input type="checkbox"/> Type IA* | <input type="checkbox"/> Type IB* |
| <input type="checkbox"/> Type II** | <input type="checkbox"/> Type II Compound** |
| <input type="checkbox"/> Please indicate if you would like the application to be dealt with in accordance with the Partnership Initiative with Ireland (N/A for mutually recognised products). | <input type="checkbox"/> Please indicate if the SPC and product literature are harmonised/joint-labelled with Ireland in accordance with the harmonisation procedures for <u>nationally</u> authorised products, or the joint-labelling procedures for mutually recognised products. |

If so please indicate product name or authorisation number in Ireland:

EU Procedures only: please complete the following

If applicable, please indicate if this is a:

- Grouped variation
- Worksharing variation

- Please indicate if the product literature is joint-labelled with Ireland in accordance with the joint-labelling procedures for mutually recognised products. For applications involving more than one product; please use a separate sheet to identify the products that are joint-labelled.

Please indicate the type of change being applied for. For grouped or worksharing variations, please tick the highest ranking variation being applied for:

Please indicate how many variations of each type are being applied for as part of a grouped or worksharing variation:

- Type IA*
- Type IB*
- Type IB*(Unforeseen)
- Type II**
- Extension** (refer to the VMD guidance note on the completion of the UK Annex. By ticking this box you are declaring that you intend to retain the change as part of the original MA.)

Type IAs:	
Type IBs:	
Type IIs:	
Extensions:	

For worksharing applications or grouped variations, please indicate how many marketing authorisations are affected by the changes:

* 3 copies of the forms and 2 copies of the data are required

** 3 copies of both the forms and the data are required

Product Name (for grouped or worksharing applications you only need to enter the first product name):

Applicant's reference number:

Address for Invoicing (if not the Marketing Authorisation Holder (MAH)):

Please list below the documents required for the variation(s) applied for (as indicated in NTA guideline and VMGN 4) and indicate the location of each in the dossier.

For grouped or worksharing variations (EU procedure only) it is important that you clearly identify the relevant documents for each change concerned. Failure to adequately provide this information may result in deferral at validation.

Title of document	Change concerned (EU procedure only)	Location in Dossier (page number)
<i>E.g. Manufacturing authorisation for 123Med Ltd</i>	<i>Type IB – addition of 123Med Ltd as finished product manufacturing site</i>	18-23



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a) Identical Changes to a number of products. Please indicate the variation category and proposed change(s) on the main application form; failure to do so will result in rejection of your application at validation.

Conditions

- 1. All the products are from the same MAH
- 2. Supporting data are identical
- 3. All applications are submitted at the same time

Documentation

- 1. Declaration that the conditions are met

b) Change of Distributor, e.g. addition or deletion of a distributor, or changes to current distributor details.

Conditions

- 1. No other aspect of the dossier is changed and the MAH remains the same

Documentation

- 1. Declaration that the conditions are met
- 2. Revised labels and package leaflet (if applicable)
- 3. A summary of the pharmacovigilance arrangements and a copy of the CV of the person responsible for pharmacovigilance
- 4. Wholesale Dealer's Authorisation No.

c) Change of legal entity of MAH, e.g. following company merger or takeover. Please note a change to the name and/or address of the MAH, which does not affect the legal entity, will be an EU derived category Type IA (1) variation.

Conditions

- 1. No other aspect of the dossier is changed

Documentation

- 1. Declaration that the conditions are met
- 2. Revised labels and package leaflet (if applicable). *Please note a revised SPC is not required; the VMD will update the latest version on your behalf and return it to you with the authorisation documentation.*
- 3. Formal letters of transfer from the current and proposed MAH
- 4. Proof of establishment of the company; only applicable if the new MAH does not hold any current marketing authorisations (MAs)
- 5. A summary of the pharmacovigilance arrangements and a copy of the CV of the person responsible for pharmacovigilance

d) Simple dosage instruction changes intended to remove ambiguity

Conditions

- 1. The change is not as a result of safety concerns
- 2. No new studies are required to support the change
- 3. The dosage regime remains the same

Documentation

- 1. Declaration that the conditions are met
- 2. Justification for the change
- 3. Revised labels, package leaflet (if applicable) and SPC



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<input type="checkbox"/>	e) Addition or change to safety warnings
Conditions	
<input type="checkbox"/>	1. No other aspects of the dossier are changed
<input type="checkbox"/>	2. No safety warnings are removed
<input type="checkbox"/>	3. No new studies are required to support the change and the proposed warnings serve to increase the protection of the user/environment/target species as appropriate
Documentation	
<input type="checkbox"/>	1. Declaration that the conditions are met
<input type="checkbox"/>	2. Justification for the change
<input type="checkbox"/>	3. Revised labels, package leaflet (if applicable) and SPC
<input type="checkbox"/>	f) Corrections or simple text layout changes to SPC and/or product literature. <i>Please note this includes the introduction of multilingual labelling.</i>
	1. Full update to Veterinary Medicines Regulations, 'SPC/label variation' (Type II timetable applies) <input type="checkbox"/>
	2. Harmonisation of SPC and product literature with Ireland; applicable to nationally authorised products only (harmonisation timetable applies) <input type="checkbox"/>
	3. Normal corrections or simple text layout changes to SPC and/or product literature <input type="checkbox"/>
	4. Joint-labelling between the UK and Ireland; applicable to mutually recognised products only <input type="checkbox"/>
Conditions (applicable to category type 1B (f.3) only)	
<input type="checkbox"/>	1. The changes are not as a result of safety concerns
<input type="checkbox"/>	2. No new studies are required to support the change and no other aspect of the dossier is changed
<input type="checkbox"/>	3. The legibility is not compromised
<input type="checkbox"/>	4. The indications/warnings etc. are the same in all languages
Documentation	
<input type="checkbox"/>	1. Declaration that the conditions are met
<input type="checkbox"/>	2. Justification for the change
<input type="checkbox"/>	3. Revised labels, package leaflet (if applicable) and SPC (SPC not required for Type IB (f.4))
<input type="checkbox"/>	4. Current SPCs for the UK and Ireland, and a proposed SPC (applicable to category Type 1B (f.2) only)
<input type="checkbox"/>	g) Abbreviated resubmission of a previously refused Type II variation
Conditions	
<input type="checkbox"/>	1. At the time of refusal of a Type II variation, the VMD has given written permission for resubmission under this category
<input type="checkbox"/>	2. The application has been resubmitted within 3 months of the date the refusal advice was issued to the MAH
Documentation	
<input type="checkbox"/>	1. Responses to the points for refusal
<input type="checkbox"/>	2. Evidence that the VMD has accepted resubmission under this category



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<input type="checkbox"/>	h) Submission made following the formal advice of the VMD
Conditions	
<input type="checkbox"/>	1. The VMD has already assessed the relevant data and formed an opinion on these.
<input type="checkbox"/>	2. The change is not required as a result of the MAH failing to keep the Part II (quality) data in accord with current practice or in line with current CVMP guidelines
Documentation	
<input type="checkbox"/>	1. If relevant, revised labels, package leaflet (if applicable) and SPC
<input type="checkbox"/>	2. Evidence that VMD has accepted submission of the variation under this category

<input type="checkbox"/>	i) Approval of mock-ups. Please note this category should be used for the assessment of mock-ups previously unseen by the VMD, because the assessment of product literature was based on text.	
	1. For an authorised pack size that has not been marketed in the UK, which the MAH now intends to introduce for sale and supply.	<input type="checkbox"/>
	2. For products not marketed in the UK, which the MAH now intends to introduce for sale and supply.	<input type="checkbox"/>
	3. Other, e.g. where mock-ups were not provided within deadline following completion of an application procedure.	<input type="checkbox"/>
Conditions		
<input type="checkbox"/>	1. The pack size(s) is(are) already authorised	
<input type="checkbox"/>	2. No new studies are required to support the change and no other aspect of the dossier is changed	
Documentation		
<input type="checkbox"/>	1. Declaration that the conditions are met	
<input type="checkbox"/>	2. Mock up(s) for the relevant pack size(s), and updated package leaflet (if applicable)	

<input type="checkbox"/>	j) Changes to the SPC and product literature of a Marketing Authorisation for Parallel Import (MAPI) as a direct consequence of the approval of a variation to the SPC and product literature for the UK authorised product	
Conditions		
<input type="checkbox"/>	1. The only changes to the SPC and product literature are those required to bring the MAPI back in line with those of the UK authorised product	
Documentation		
<input type="checkbox"/>	1. Declaration that the conditions are met	
<input type="checkbox"/>	2. Revised labels, package leaflet (if applicable) and SPC	

<input type="checkbox"/>	k) Changes to the details of the marketing authorisation holder's pharmacovigilance system.	
Conditions		
<input type="checkbox"/>	1. No other aspect of the dossier has changed.	
Documentation		
<input type="checkbox"/>	1. Detailed description of the pharmacovigilance system with the change identified	
<input type="checkbox"/>	2. A copy of the CV of the person responsible for pharmacovigilance	



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Guidance on the completion of the UK Annex

1. The UK Annex should be completed and submitted with every variation application.
2. **For EU procedures**
 - 2.1 To be completed when applying for a change(s) to a mutually recognised product(s), which is dealt with on a European level. Please complete the 'EU Procedures only' box.
3. **For National procedures**
 - 3.1 To be completed when applying for a change to a nationally authorised product, i.e. a change that is either listed in the formal application form or in the UK Annex. Please complete the 'National procedures only' box.

OR
 - 3.2 To be completed when applying for a change to a mutually recognised product that is dealt with on a national basis, i.e. a change that is not listed in the formal application form, but is listed in the UK Annex. Please complete the 'National procedures only' box.
4. **Extensions**
 - 4.1 An extension may only be included in a grouped variation if the change is to be retained as part of the original MA, i.e. 'rolled back' into the original MA and not granted an MA in its own right. For an extension application that includes additional changes via a grouped variation, you should submit a Marketing Authorisation application form, along with an application form for a variation to Marketing Authorisation, and the UK Annex. All changes required will be assessed via a timetable for an extension application.
 - 4.2 For an extension application that is not part of a grouped variation, you should only submit a Marketing Authorisation application form.
5. **Grouped variations**
 - 5.1 For applications involving more than one product you only need to enter the first product name on page 2 of the form.
 - 5.2 Please be aware that for Type IB/II/Extension led grouped variations involving several products, the procedure number for all products in the group should use the same stem (highlighted in bold), e.g. UK/V/**1234**/001, UK/V/**1234**/002. You should tick 'Grouped variation' for these.
 - 5.3 When applying for the same change(s) to multiple products that do not use the same stem number (as described above), you must submit separate applications. However, these will be considered a 'grouped' variation for fees purposes. You should not select 'Grouped variation' for these. For this to be applicable, the changes concerned must fall within one of the cases listed in Annex III of regulation 1234/2008.