EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Variation eAF v1.24.0.0

Changes introduced in v1.24.0.0 of the variation form
Guidance for applicants – **Updated 26.10.20**

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Go-live of the new version 15th September 2020
Mandatory use from 15th of December 2020

Summary of changes in v1.24.0.0

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The v1.24.0.0 provides a **major technical change in the variation application form** (H&V)

- Connection between sections 1 and 3 of the form;
  - The selections made in section 1 'Type of Application' now directly affects the section 3 and depending on the selection, only the relevant scopes are available for selection in section 3.
  - **Note**: It is very important to note that **any changes in section 1 'Type of Application'** will lead into **deletion of any already selected scopes** in section.
- The **variation scopes** are now selected using **controlled terminology lists** (from RMS) instead of hard coded lists. This will bring significant **performance improvements** as the form is now much shorter and lighter
- The 'Conditions and Documentation' are now **integrated** in to the form and applicable conditions and documentation are automatically shown together with the scope(s) that have been selected. This means that **separate Annex to the application form** should no longer be provided. The applicant can indicate, using a tick box, the relevant selections and additionally, a free text field has been provided to include any justification/details for example why certain condition is not met/document is not provided or simply to provide more details

Important reminders about using the eAF forms

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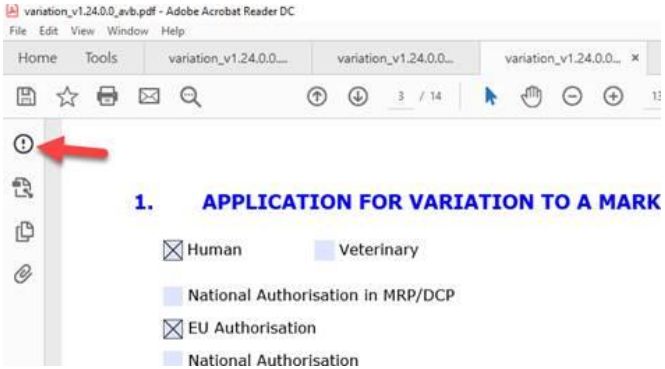
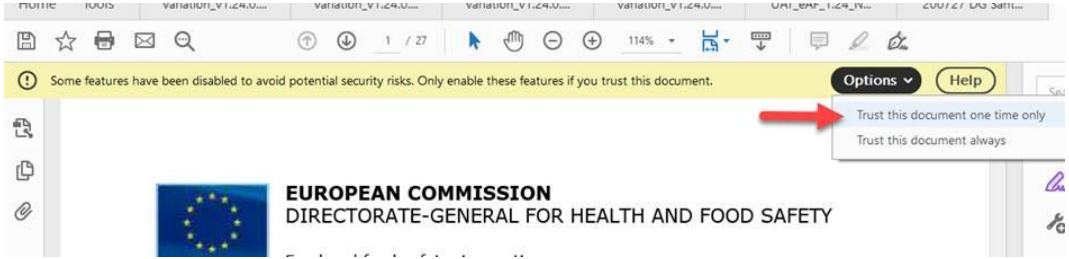
- The eAFs should be edited using **Adobe Reader DC**
- Please note that the conditions and documentation provided as a part of the scope, unfortunately do not contain the numbering from the classification guideline and the ordering of the conditions/documentation may be different from the classification guideline. We are currently looking at options in relation to this issue, however, regardless there is no need to provide separate annex as this could lead into discrepancies and additional work.
- Please note that the forms must be signed using an image of a signature or a signature snippet. **Adobe sign** or **other digital signature** tools **must not** be used
- Please note that imports of data from an older version do not work when there are significant changes to the form from the previous version. For example, it is not possible to import data from variation form v1.23.x.x due to very extensive DES changes
- If you experience any issues with the forms – please report these to the EMA Service Desk portal immediately
- If you notice that there is an error in the newly introduced RMS variations list, for example a typo, a **missing scope**, error in the Conditions or Documentation etc, please report these to the EMA Service Desk portal immediately. In most cases the missing scopes are not intentional!

Accessing control terminology lists – very important

- In order to access the control terminology lists, the forms **must be trusted** first
- Please save the form on your local drive – potentially with another name – and open the saved form using **adobe reader DC**. It is **important to use adobe reader DC to edit the forms** instead of adobe acrobat or acrobat pro **as using these will result in issues with locking the forms and may lead to rejection**
- Once you open the form, there should be an **exclamation mark** on the top of the left hand pane. If the pane is closed, click the small sideways arrow to open the pane
- When you click exclamation mark, a yellow banner will open across the top, please select trust this document one time only

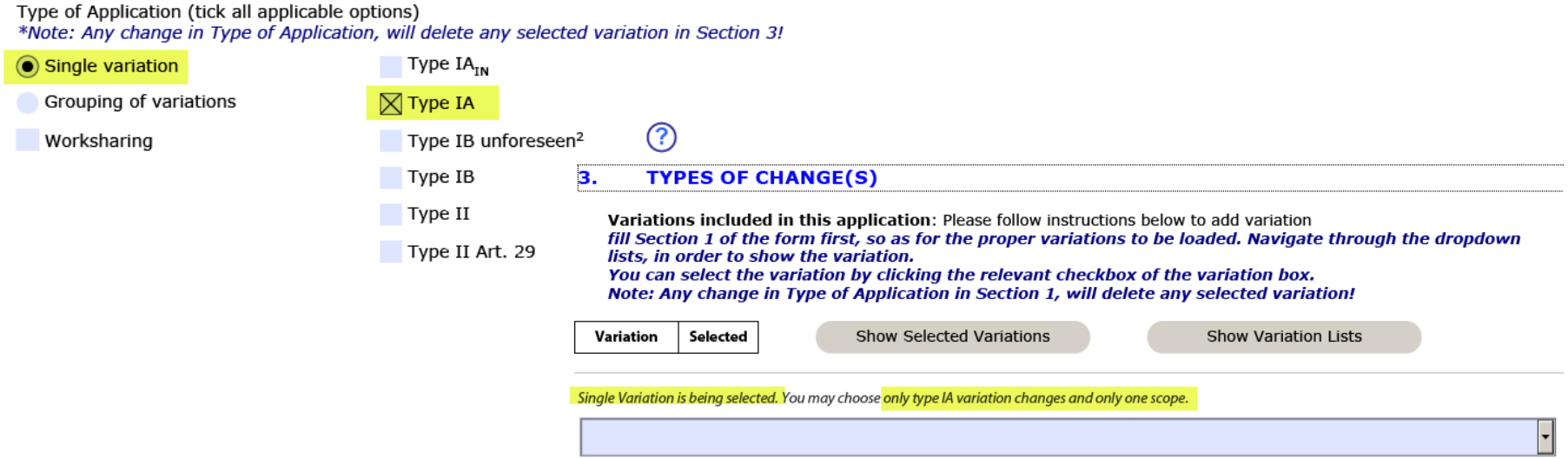




Details of the changes - Connection between sections 1 and 3

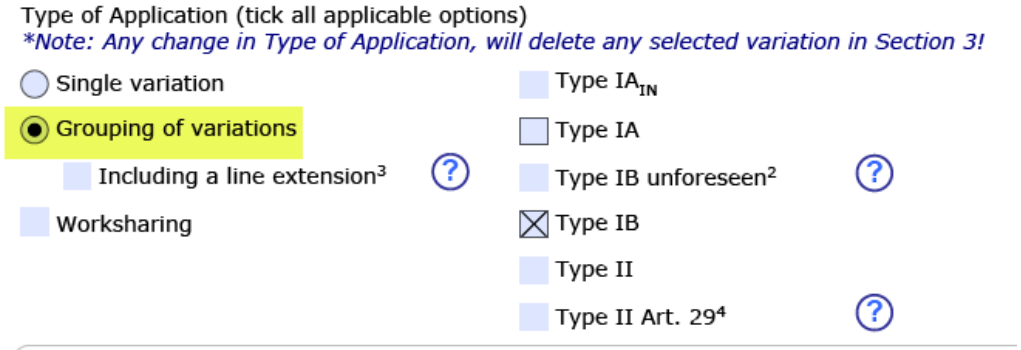
The selections made in section 1 'Type of Application' will now directly affect the section 3 and depending on the selection, only the relevant scopes are available for selection in section 3.

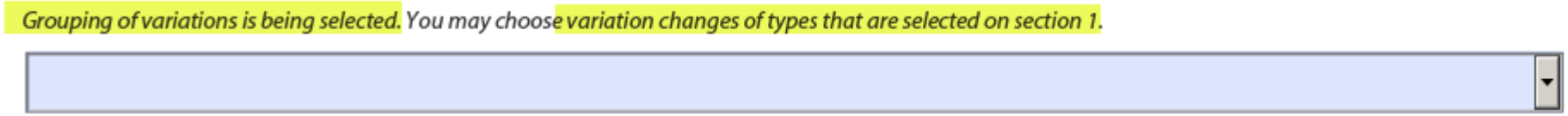
If a 'single' variation has been selected in section 1, it is only possible to select a single scope in section 3



Details of the changes - Connection between sections 1 and 3

If a grouping has been selected in section 1, a form validation error will be raised if only single scope is selected **with the exception of Type IA_{IN} or Type IA variations** where a single scope can be selected without a validation error

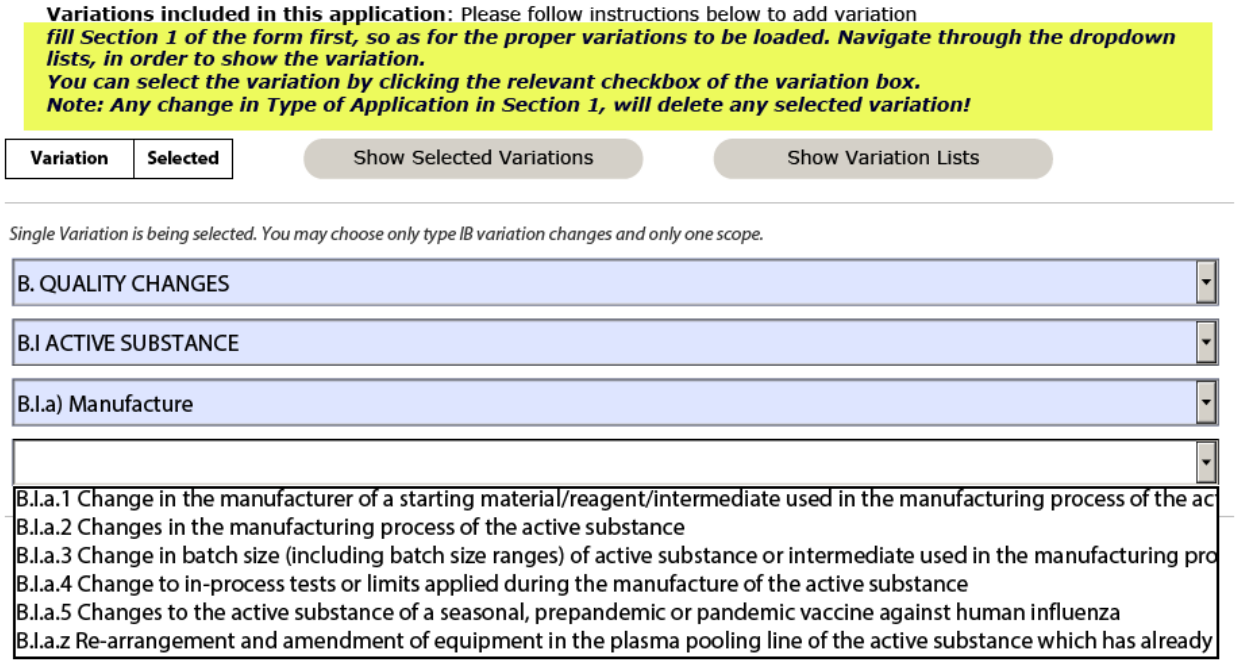




Details of the changes - Connection between sections 1 and 3

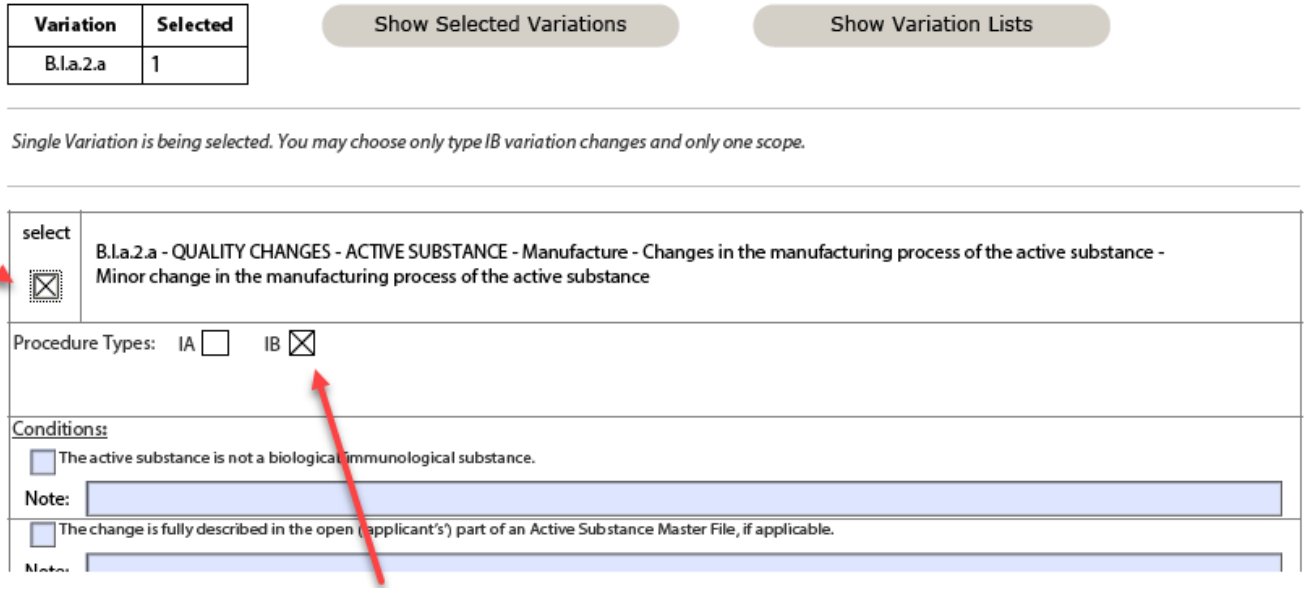
The selection of scopes in section 3 is done by drilling down dropdown menu which displays different available scopes based on the selections in section 1

Please note that **any changes in Type of Application in section 1 will delete any selected variations!**



Details of the changes - Connection between sections 1 and 3

In order to **select** the chosen scope, it is important to tick the 'select' tick box. If this box is not ticked and you make changes in the dropdown menu, the selected options will be deleted



If only one procedure type, for example IB is possible, based on the selection in section 1, or due to classification guideline, the procedure type will be automatically ticked by the system and cannot be manually changed

Details of the changes - Connection between sections 1 and 3

For Type IA and Type IA_{IN} the implementation date and implementation note are available.

Single Variation is being selected. You may choose only type IA variation changes and only one scope.

B. QUALITY CHANGES

B.II. FINISHED PRODUCT

B.II.b) Manufacture

B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product

B.II.b.2.a Replacement or addition of a site where batch control/testing takes place

select	B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

Procedure Types: IA ☒ IB ☐

Implement. Date: Implement. Note:

Conditions:

☐ The site is appropriately authorised.

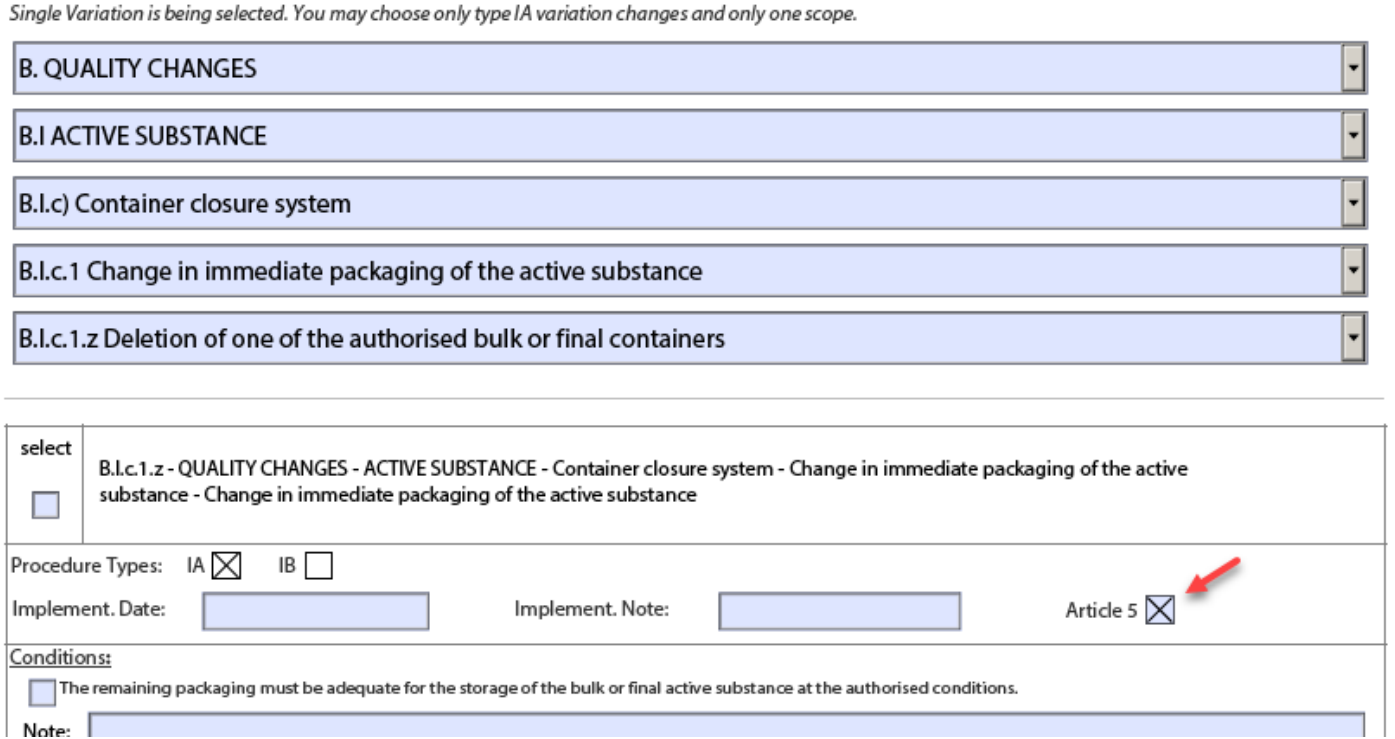
Note:

☐ The product concerned is not a biological/immunological medicinal product.

Note:

Details of the changes - Connection between sections 1 and 3

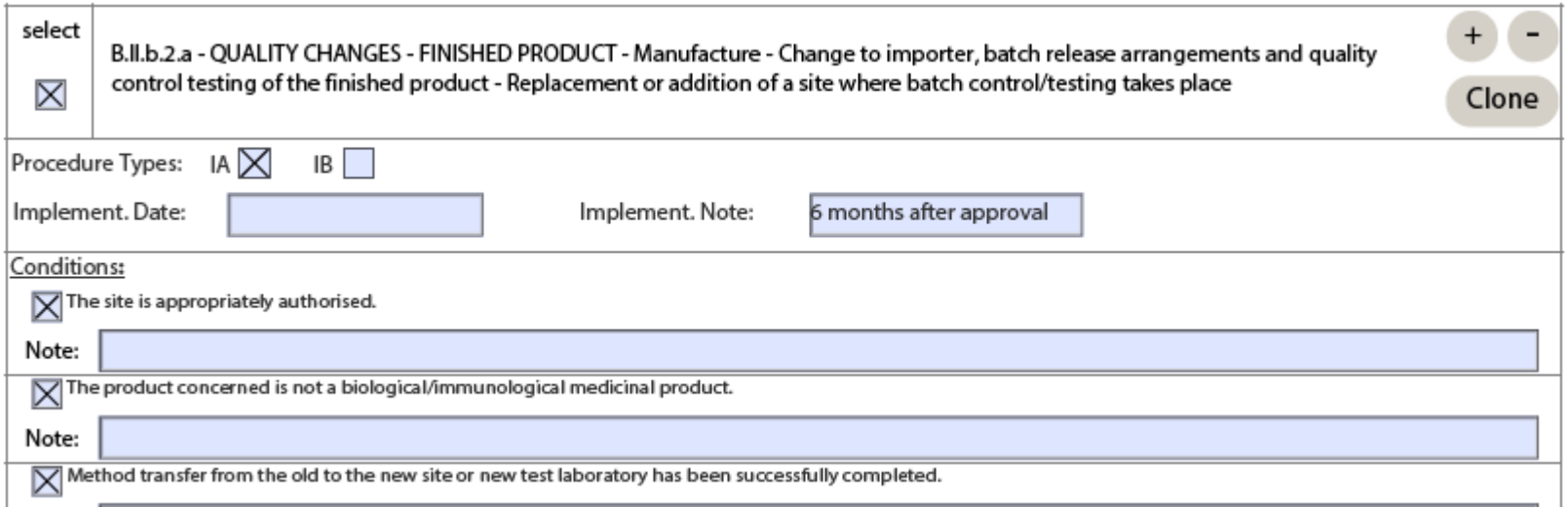
Where relevant the Art 5. checkbox will be automatically ticked and cannot be manually unticked.



Details of the changes - Connection between sections 1 and 3

When grouping is selected in section 1, and different procedure types have been selected in section 1, you will need to **manually** select the procedure type.

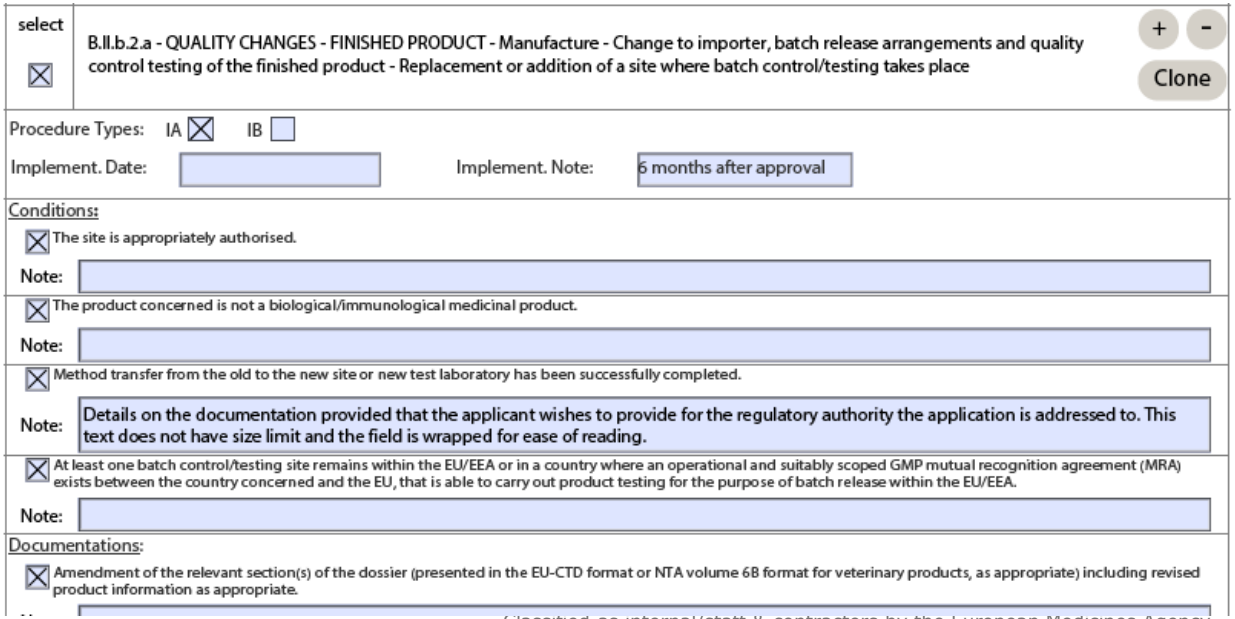
+ and – buttons, as well as 'clone' button to add additional scopes/clone scopes you have selected are available



Details of the changes - Connection between sections 1 and 3

The relevant Conditions and Documentation are now available directly in the form and those relevant to the selected procedure type and scope are shown as a part of the scope.

If the condition/documentation tick box is not ticked, the free text field is **mandatory**. The free text field is always available and any necessary information can be included in it, as previously done in the separate annex to the application form.


select

B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place

+ - Clone

Procedure Types: IA ☒ IB ☐

Implement. Date:

Implement. Note: 6 months after approval

Conditions:

☒ The site is appropriately authorised.

Note:

☒ The product concerned is not a biological/immunological medicinal product.

Note:

☒ Method transfer from the old to the new site or new test laboratory has been successfully completed.

Note: Details on the documentation provided that the applicant wishes to provide for the regulatory authority the application is addressed to. This text does not have size limit and the field is wrapped for ease of reading.

☒ At least one batch control/testing site remains within the EU/EEA or in a country where an operational and suitably scoped GMP mutual recognition agreement (MRA) exists between the country concerned and the EU, that is able to carry out product testing for the purpose of batch release within the EU/EEA.

Note:

Documentations:

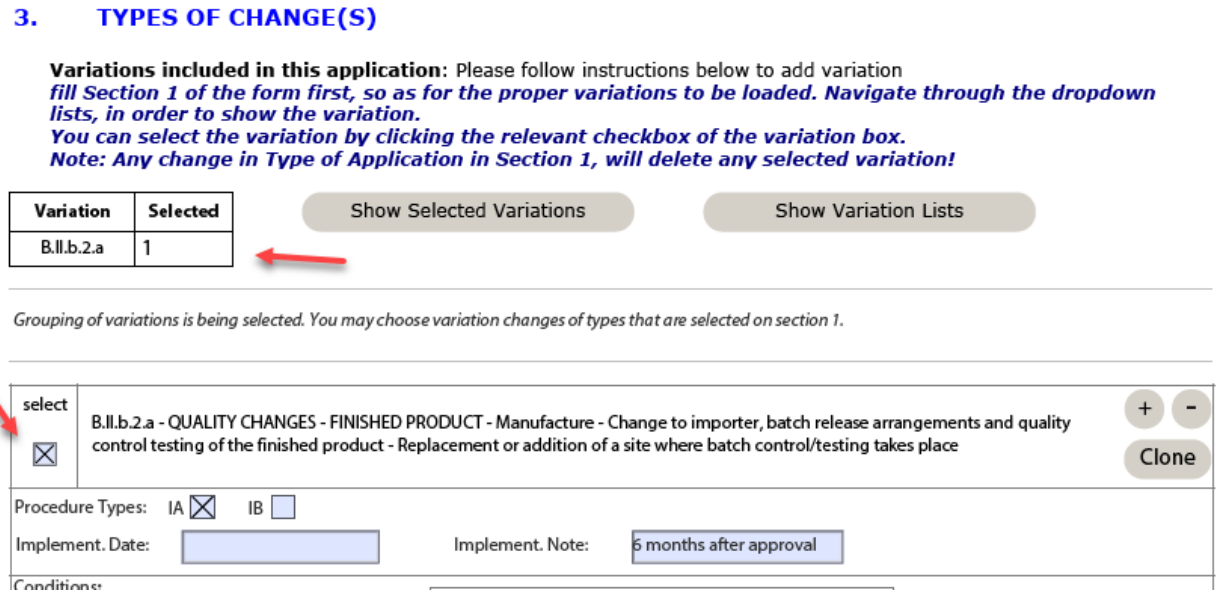
☒ Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate) including revised product information as appropriate.

Please note:

The separate annex is no longer expected to be provided as a part of the submission.

Details of the changes - Connection between sections 1 and 3

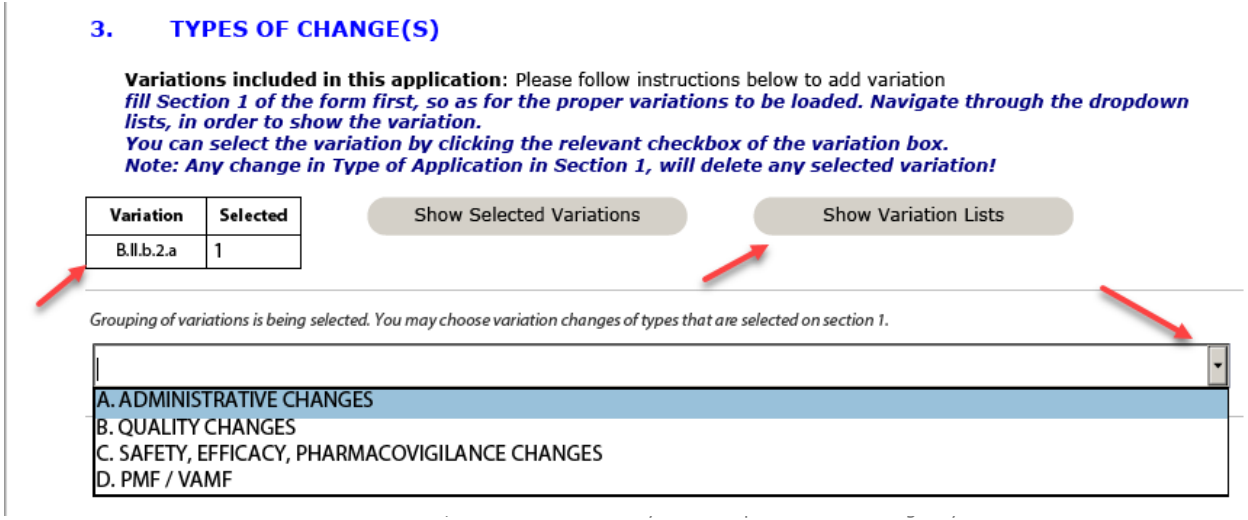
Always ensure that you have **selected the scope** and ensure that the details are shown in the summary box before moving on. This is especially important for grouping variations if you need to select a different scope as this will be done by repeating the selections using the dropdown menu.



Details of the changes - Connection between sections 1 and 3

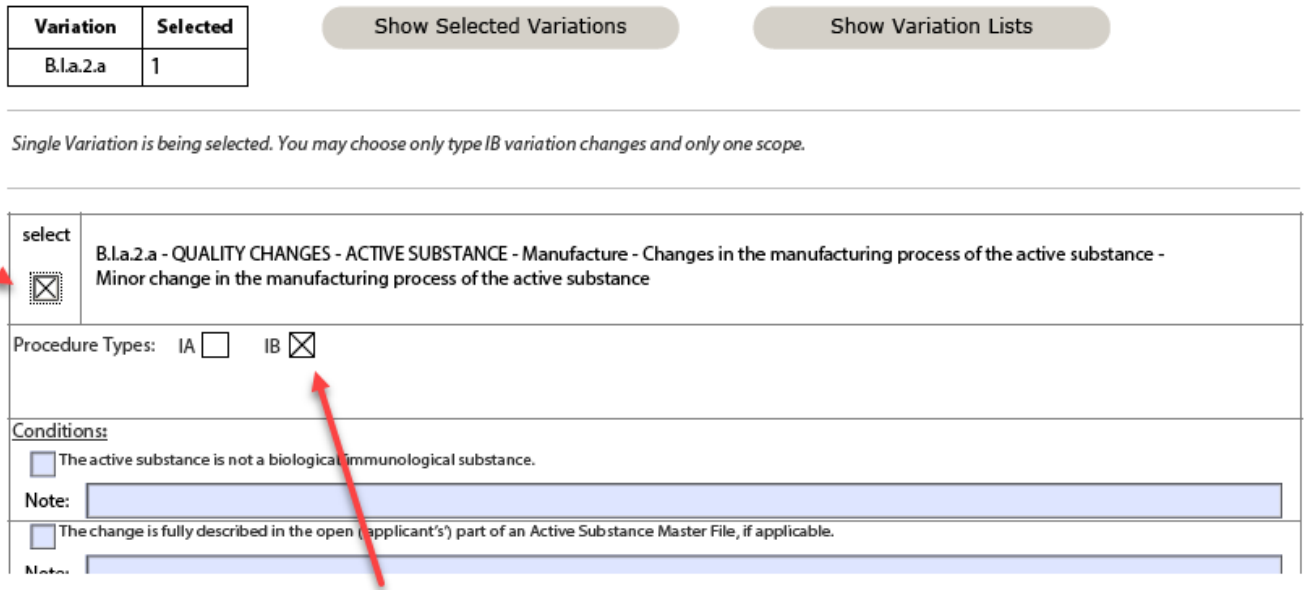
For groupings, if you have used the 'Show Selected Variations' button and wish to continue adding different scopes, please click the 'Show Variation Lists' which will display a 'fresh' dropdown menu to continue scope selection.

If you have not used 'Show Selected Variations' button and wish to continue adding other scopes, simply start over by selecting the relevant scope using the required level of detail – as long as you have selected the previous scope and can see it in the summary box, you are not overwriting the previous selection.



Details of the changes - Connection between sections 1 and 3

In order to **select** the chosen scope, it is important to tick the 'select' tick box. If this box is not ticked and you make changes in the dropdown menu, the selected options will be deleted



If only one procedure type, for example IB is possible, based on the selection in section 1, or due to classification guideline, the procedure type will be automatically ticked by the system and cannot be manually changed

Any questions?

Further information

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