24 June 2025

Guide to navigation – June 2025 update

Product Lifecycle Management Portal – Human Variations eAF

CAPs and non-CAPs

Version 1.9

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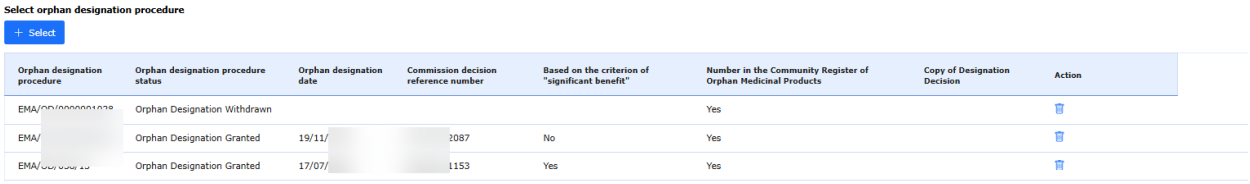


Acronym key and glossary terms

Abbreviation	Description
ATC	Anatomical Therapeutic Chemical code
eAF	Electronic Application Form
EMA	European Medicines Agency
FAQ	Frequently Asked Questions
IT	Information Technology
MAH	Market Authorisation Holder
OMS	Organisation Management Service (part of SPOR)
PLM	Product Lifecycle Management
PMS	Product Management Service
PSMF	Pharmacovigilance System Master File
SPOR	Management Services for Substances, Products, Organisations and Referentials

1. Purpose and Context

IMPORTANT NOTE FOR USERS: The PLM Portal web-based eAF is now open for all types of variation applications for all products, including those authorised through purely national procedures (NP), mutual recognition procedure (MRP) and decentralised procedure (DCP). The use of the web based eAF for non-centrally Authorised products (non-CAPs) submissions to the NCAs is recommended from 26th May 2025.

Please note that is **strongly recommended** to use the web based eAF for **Centralised Procedure applications**. It is also possible and recommended to use the web based eAF for mixed **CAP/non-CAP EMA-led worksharing applications**.

We **very strongly** encourage the non-CAP MAHs to use this period of time to familiarise themselves with the system and start using the web-based form, where possible, instead of the interactive pdf eAF. We invite all users to pay attention if there are any issues in the new web based eAF that would prevent the use of the form in **any** scenarios. Please provide the feedback on change requests and issues to EMA in a consolidated way (ideally through industry associations) via the EMA service desk.

If you are using the web-based form and you have an issue, please report these through the service desk.

1.1. Purpose of this guide

This guide aims to support the users of the PLM Portal - eAF in navigating through the platform. More specifically, the guide has been produced to show users how to access the PLM Portal - eAF, as well as prepare application forms.

Please note that this guide is a living document which will be updated **regularly**. It describes some issues in the form functionality and aims to provide workaround solutions. Please refer to the user guide before raising questions via the Service Desk as your question may already be addressed in this guidance.

Please note that, although this version is updated this is still an early version of this guide and it may contain errors and incomplete information.

1.2. Preliminary requirements

To access the PLM Portal eAF all users are required to have:

- *an active **EMA user account**, and,*
- ***user access role(s)** assigned to that account.*

Registration needs to be done only once. For information on how to request an EMA account and how to an appropriate PLM Portal - eAF role (these are two separate actions), please consult the separate *PLM Portal - eAF - Guide to Registration* document.

1.3. Supported Browsers

The PLM Portal - eAF can be accessed on any modern Web Browser, including but has only been tested with Google Chrome (latest version) and Edge (including the new, Chromium-based Edge). No official testing has been done using other browsers, such as Safari 12 and above, Firefox (latest version), Vivaldi, etc.

2. Navigation through the PLM Portal - eAF

2.1. Creating an application form

2.1.1. How to access the PLM Portal eAF

- In Production environment, the PLM Portal - eAF can be accessed via the following link: https://plm-portal.ema.europa.eu/

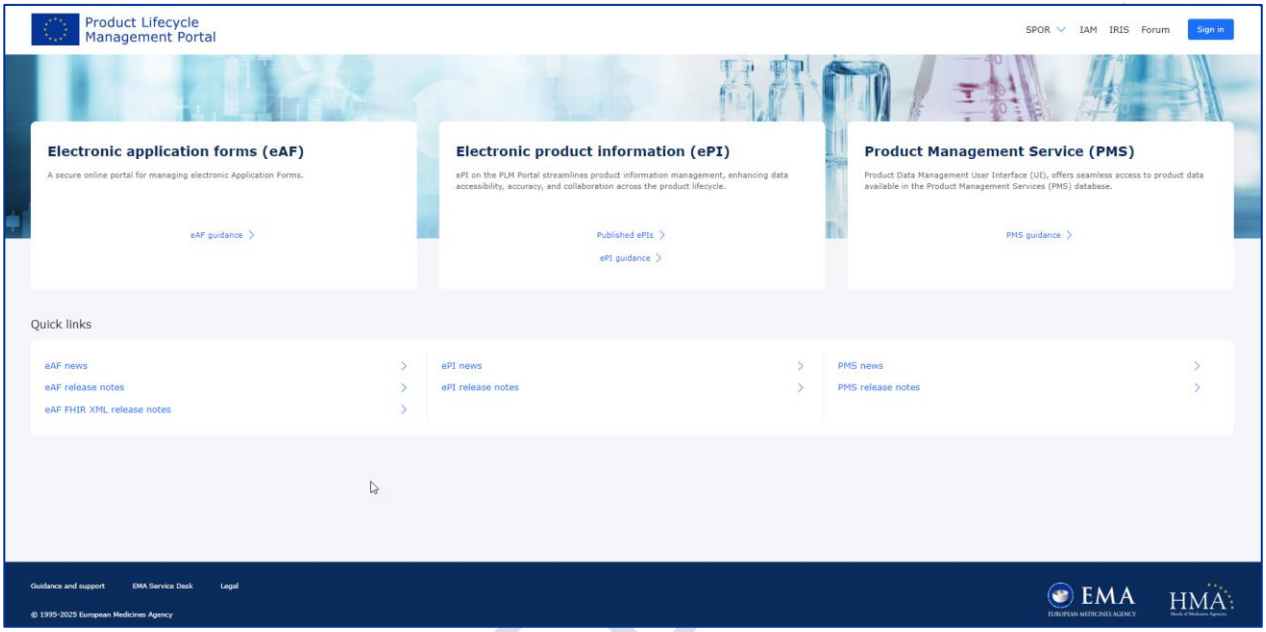


Figure 1 - Sign-in

2.1.2. How to create a new electronic Application Form

Users with an active EMA account and (a) either with the eAF Applicant Manager or the eAF Applicant Coordinator role if they originate from the pharmaceutical industry or (b) with the eAF Competent Authority User if they originate from a NCA can create a new Application Form. Please refer to the PLM Portal - eAF guide for registration

1. Sign into the PLM Portal – eAF

   You must click on the **Sign In** button, which is available at the top right corner of the PLM Portal - eAF home page and at the centre-left of the sign in page after the Sign in option at the top of the page has been clicked.

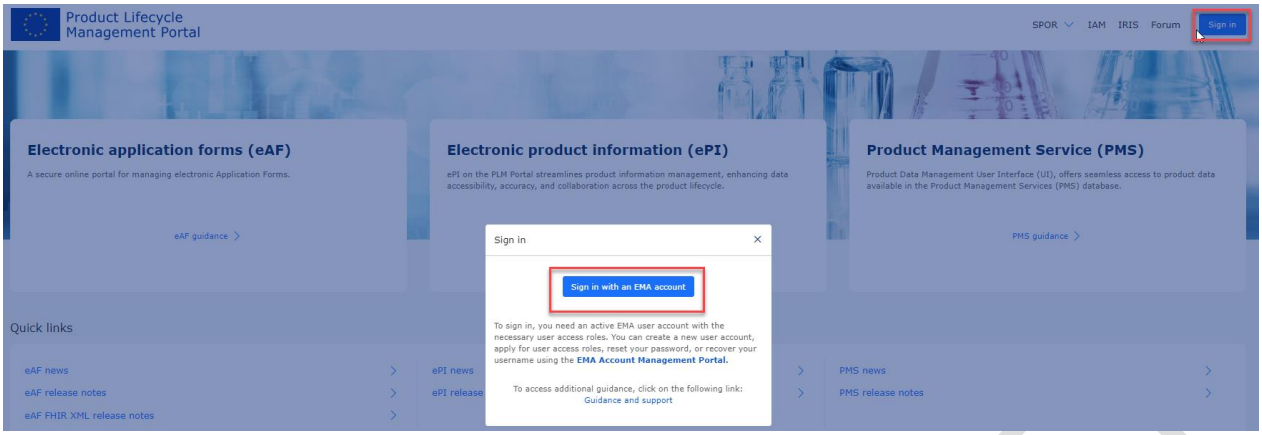


Figure 2 - Sign-in button

2. Once you are signed in to the system, on the home page, click on "Application Forms" in the centre-left or in top navigation bar,

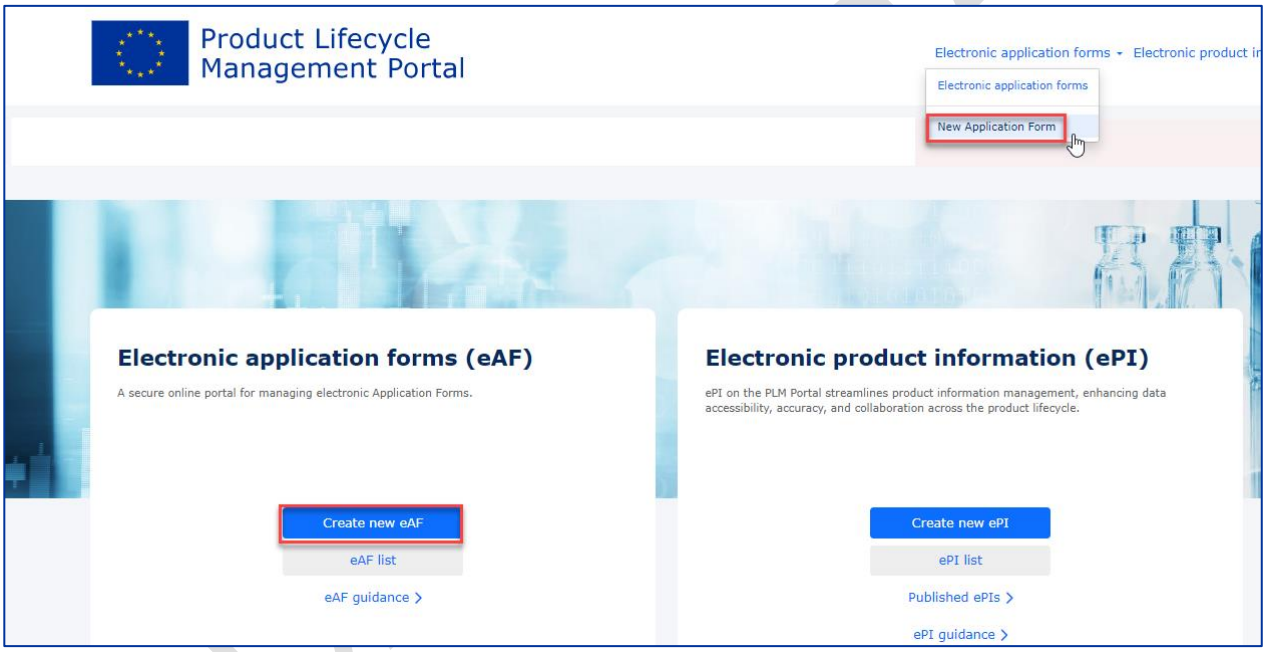


Figure 3 - New Application Form

3. Click on Create new eAF/New Application Form

You will be prompted with the *Draft Application Form* page. In order to complete the Application Form creation procedure, and be able to go back to that Application Form at any point in time in the future, you must complete:

- *The step 1. Select Application Details and,*
- *Optionally, the step 2. Add Co-Author.*

In the *1. Select Application Details* screen:

- The **Application Form Type** is now auto selected to reflect the only available form type (*Variation Form Human*). In future when additional form types become available, the form type can be selected from the dropdown menu.

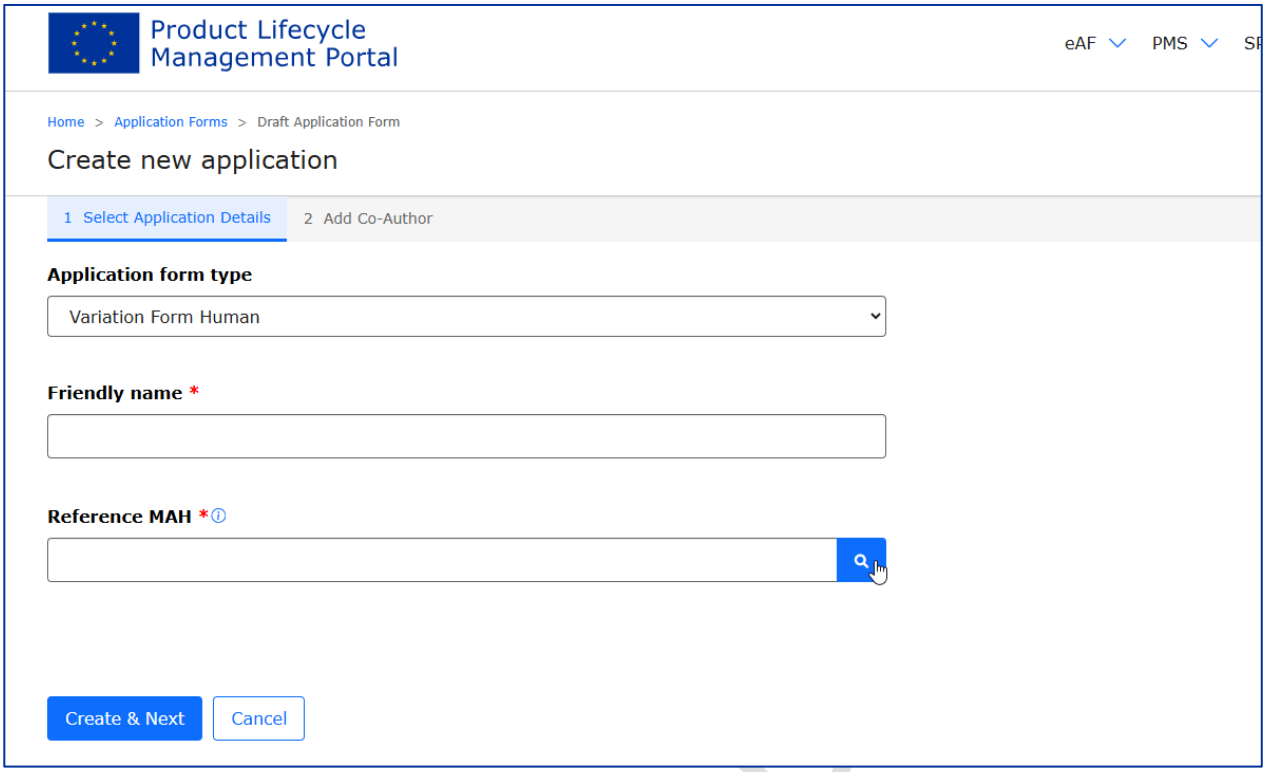


Figure 4 - Application Form Type

- Add a **Friendly Name** (e.g.: *Productname Type II quality).* Ideally this name should be **meaningful** as it will help you to identify the application form from a potentially large list of other application forms. For example, the product name and procedure number -if known- might be helpful attributes.

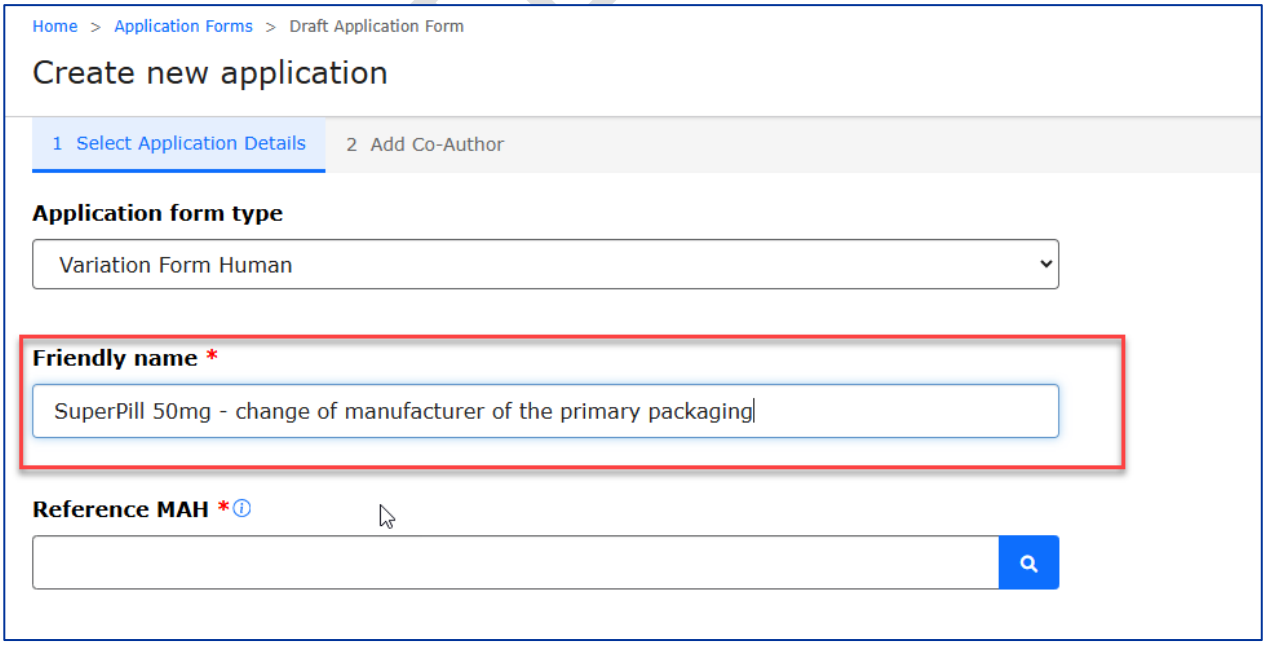


Figure 5 - Application Details

- Please note that it is now possible to change the originally given Friendly name.

- To change or update the Friendly name, please select the option '**Rename application form**' from the application list right hand menu

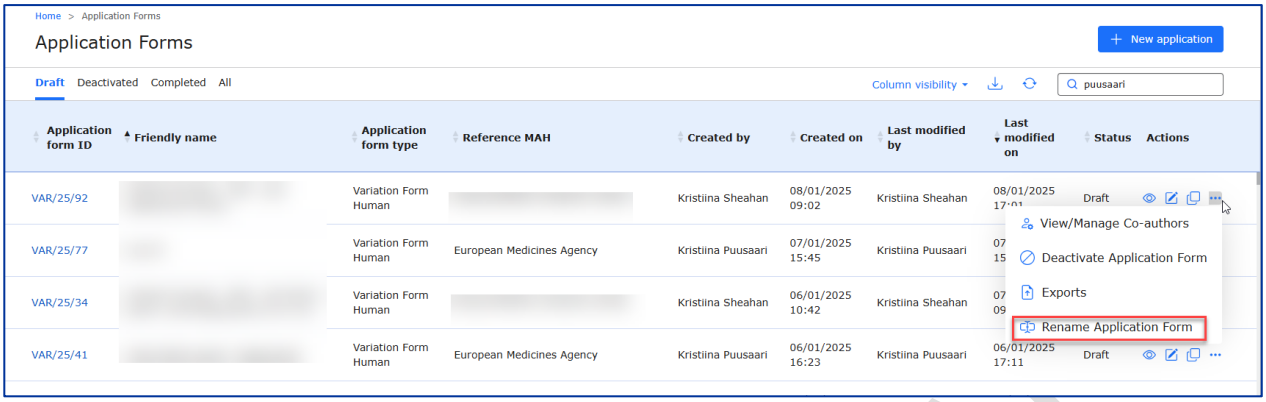


Figure 6 - Re-name Applicatiuon Form

- Select the **Reference MAH**, by using the 🔍 icon (e.g.: *UAT-LOC11*) – you can select the MAH from the list displayed to you. If you are affiliated to multiple different organisations, you can filter the list using various attributes, such as the LOC or ORG-id, the company name or address.

- **NOTE:** *In case of worksharing or supergrouping variations, it is possible to only add one MAH in the form, this should be the 'Reference MAH'. Further information on the reference MAH can be found from the EMA/CMDh explanatory notes on variation application. It is not possible to provide the MAH details for the other MAHs whose products may be included in the form.*

In the interactive pdf, one can filter organisations with multiple attributes at the same time, for example company name and the country. This is not possible currently in the PLM Portal eAF. To get a better, more matching result, please type for example a part of the address or search using the LOC or ORG id.

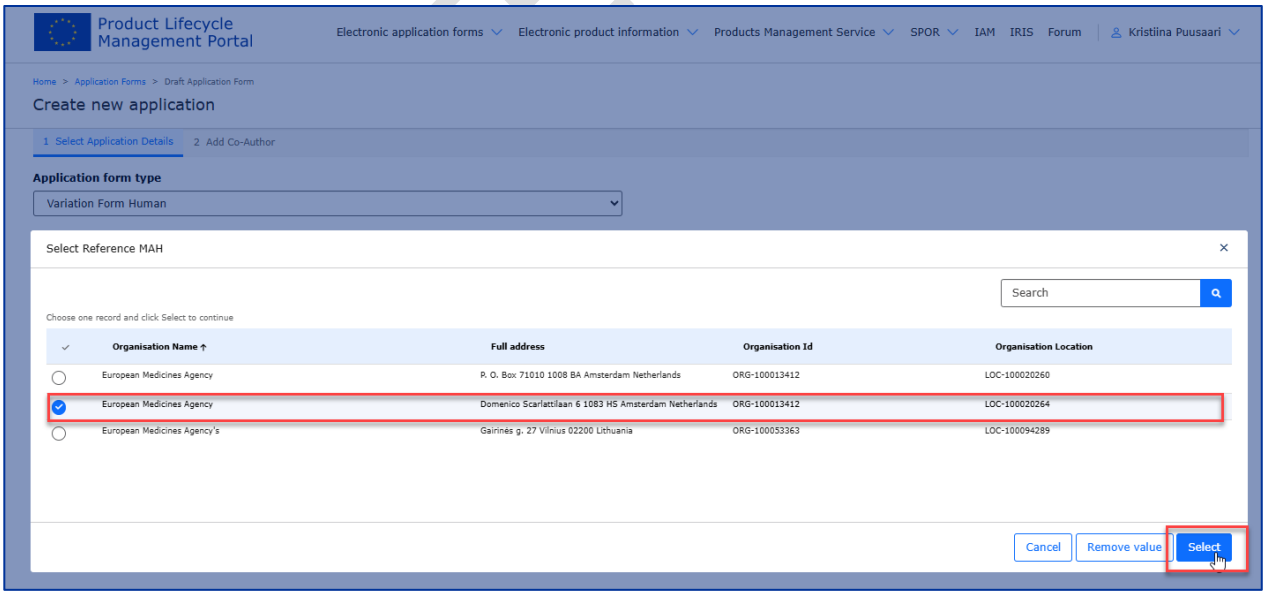


Figure 7 - Reference MAH

- *Click* Select *to select the MAH from the list. Depending on your role and affiliation, you may only have 1 or more options to select the MAH from. After you have selected the MAH, it is still possible to change it at this point if you realise it is not the correct organisation/location.* You

can remove the organisation by clicking the X next to the magnifying glass. At this point, you can select or perform a search/filtering as many times as needed.

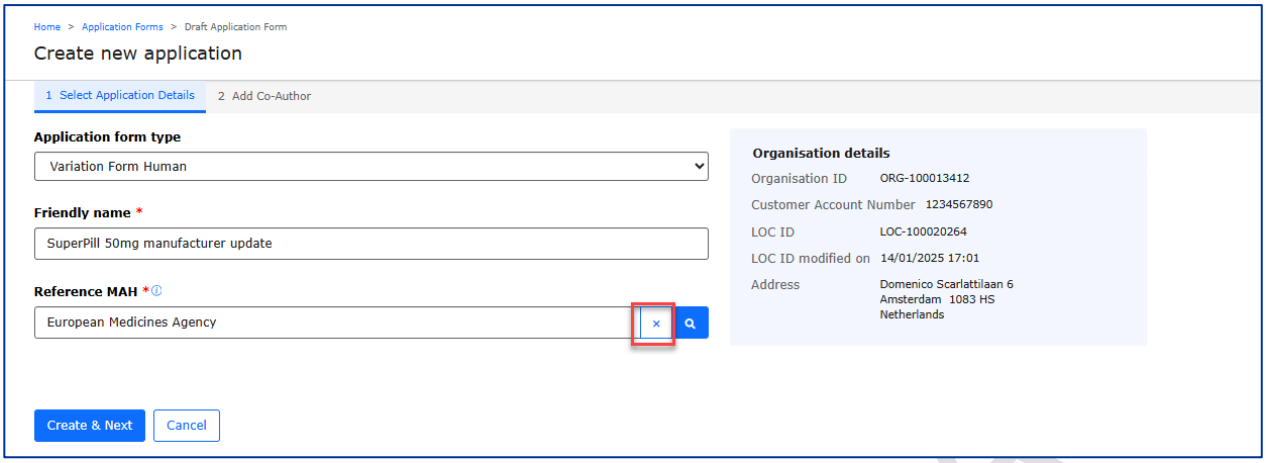


Figure 8 - Create & Next Button

4. Click on the Create & Next button to confirm the selection of the MAH and to create the application form.

   Note: it is **not possible** to **change** the MAH after the 'Create and Next' is clicked. If you realise after this that the organisation you have selected should be changed, you will need to create a new application form.

In the *2. Add Co-Author* screen, you may:

Click on the Add Co-author button – to add co-authors to that Application Form

- *Click on the Previous button – to go back to the 1. Select Application Details screen*
- *Click on the Next button – to skip adding any co-author or as soon as you are ready with adding co-authors to that Application Form*

  (by default, as creator of the Application form, you are nominated as an author of that Application Form)

On this page you can also see all other users (Coordinators) who have implicit access to this application form. This means users that are affiliated with the selected MAH and have appropriate eAF coordinator user role.

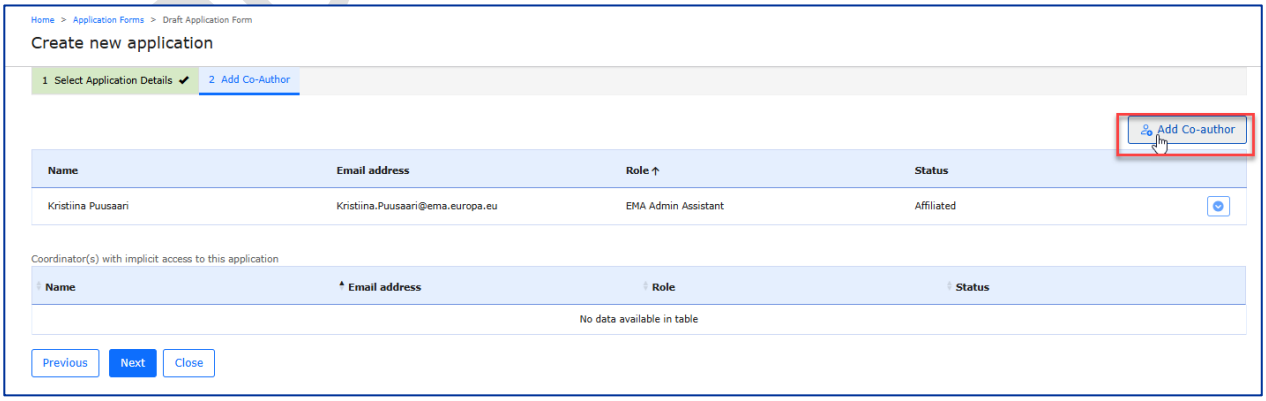


Figure 9 - Add Co-Author

Select user(s) from the 'My Organisation Affiliate(s)' tab. Alternatively, you may select user(s) from the 'From Other Organisation(s)' tab, by searching for an author's e-mail address.

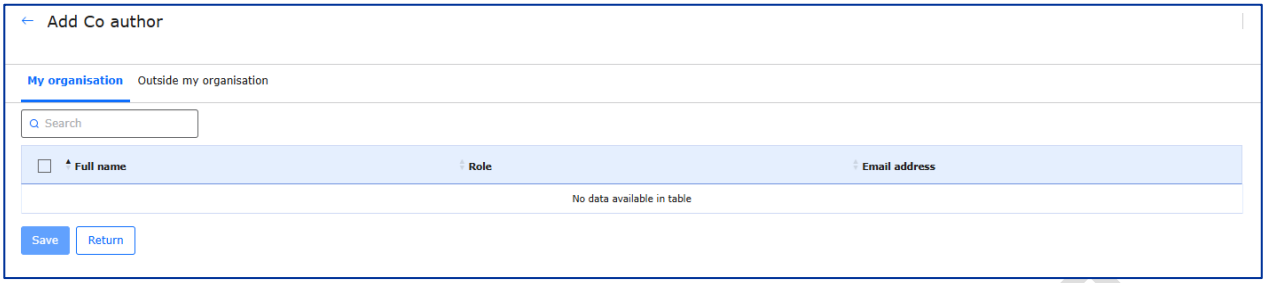


Figure 10 - My Organisation Affiliate(s)' Tab

In the 'My Organisation Affiliate(s)' tab, you will see other users from the organisation(s) with whom you have an access role.

NOTE: *Adding any co-authors will give these colleagues access to* ***Commercially Confidential Data*** *via the FHIR xml contained in the pdf export. This information contains details that are not visible via the web user interface (the application form UI) nor the PDF itself, however, details on Manufacturers and ingredients are listed on the XML attached to the pdf export.*

Please note that in one go you can add:

- *one or multiple users from the 'My Organisation Affiliate(s)' tab, or,*
- *only one user from the 'From Other Organisation(s)' tab.*

Click on the Save button

You will be prompted with a list of all added co-authors for that Application Form. It is to be noted that only users with the Role Status '**Affiliated**' can access / edit an Application Form.

There are **no automated** notifications **sent** when co-authors are added.

You **can send** an email notification directly from the PLM Portal eAF to the co-author(s) from **other** organisations whose role status is set to '**pending**'. This will alert the added co-author(s) that they have been added to the application form. This notification is not automatically sent.

If you are adding a co-author from another organisation, a **very important note** related to **Commercially Confidential Data** (CCI) is displayed on this screen.

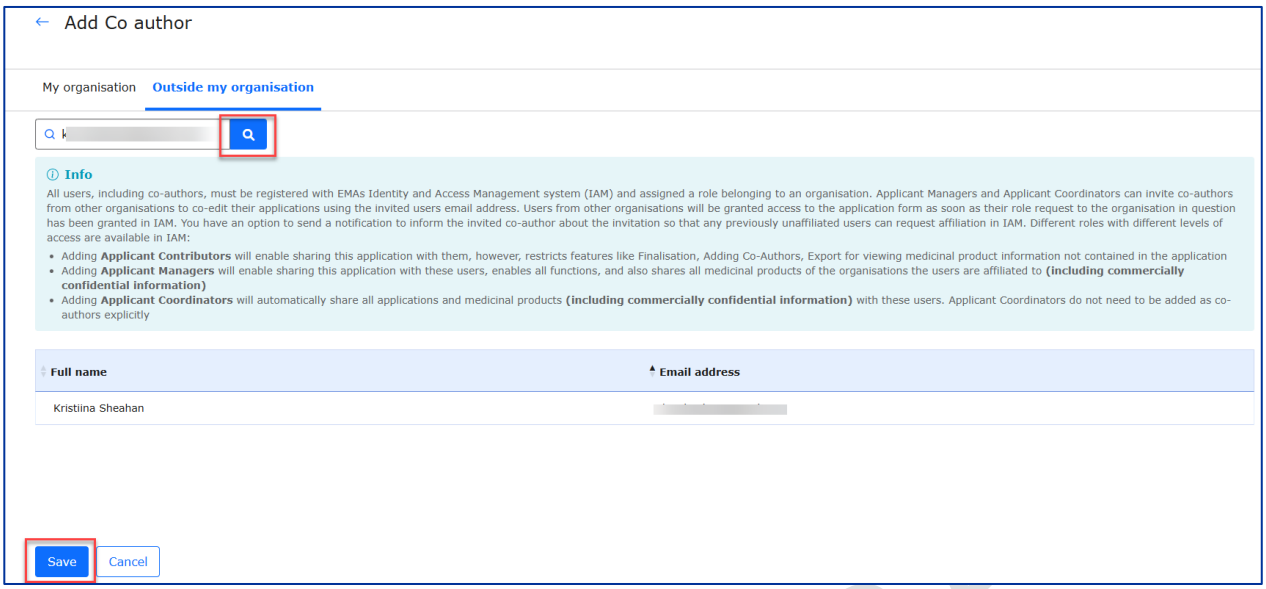


Figure 11 - Add Co-author

You may wish to send a notification to those users whose Role Status is '**Pending**'. This notification informs the user to create an access role request for that organisation.

If you wish to add a co-author to already created application, you will need to return to 'menu' of 'Application forms' and right click to select the application form into which you would like to add the authors.

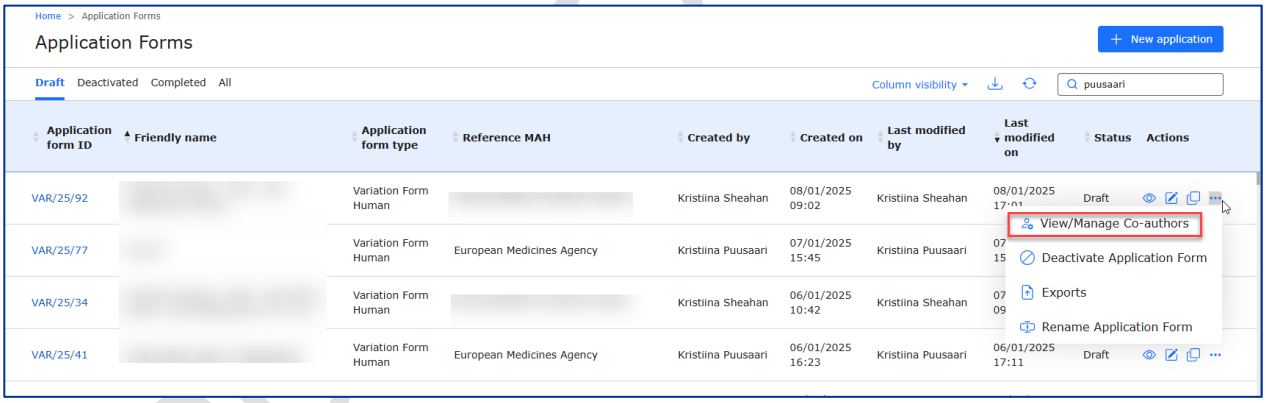


Figure 12 - View/Manage Co-authors

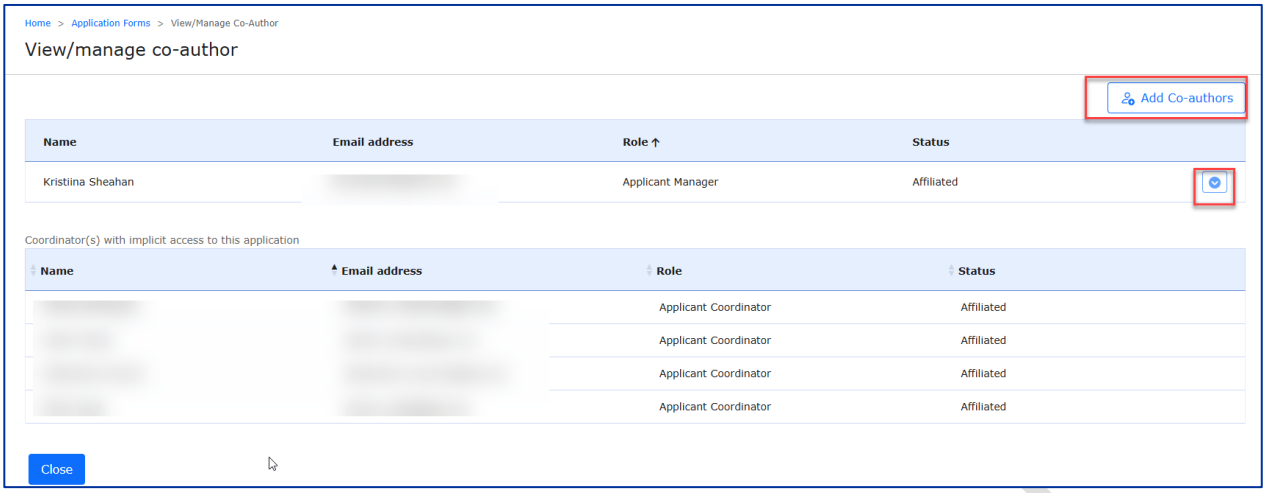


Figure 13 - Add Co-author

2.1.3. How to access previously created/edited electronic Application Form(s)

Industry users with an active EMA account and with the eAF **Applicant Manager** role can edit existing Application Forms which have been created by them;

Industry users with an active EMA account and with the eAF **Applicant Coordinator** role can edit an any existing Application Forms from the organisation(s) on whose behalf they will be acting;

NCA users with an active EMA account and with the eAF Competent Authority User role can edit any existing Application Form from their Member State.

1. Sign into the PLM Portal - eAF
2. On the home page, top navigation bar, click on Application Forms or navigate directly from the 'Application forms' link in the middle of the screen
3. Click on Application Forms

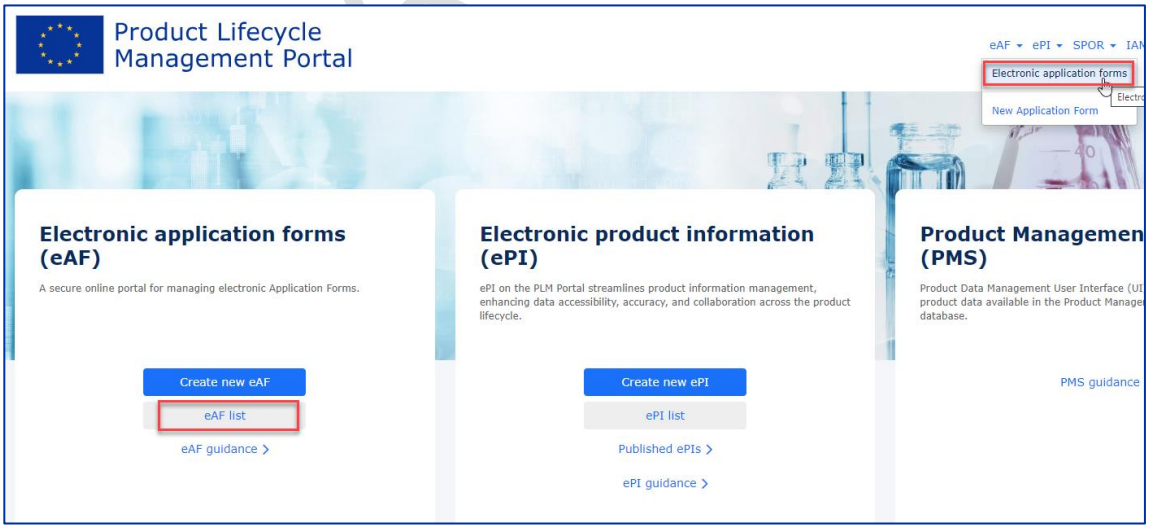


Figure 14 – eAF List

Depending on your access role(s)/permissions, you will see a list of Application Forms available for you:

- *eAF Applicant Contributor role – Application Form(s) in which you were **added** as co-author;*
- *eAF Applicant Manager role - Application Form(s) created by you or in which you were added as co-author;*
- *eAF Applicant Coordinator role – all the Application Form(s) of the organisation(s)/affiliate(s) for which you have the Coordinator role;*
- *eAF Competent Authority User role - all the Application Form(s) of the country for which you have the Coordinator role.*

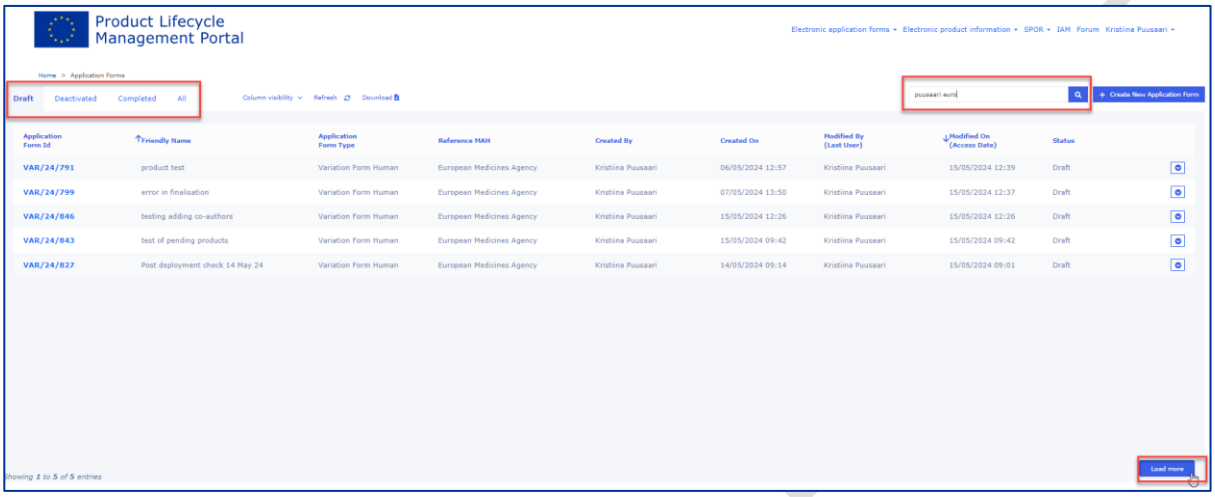


Figure 15 - Application Forms

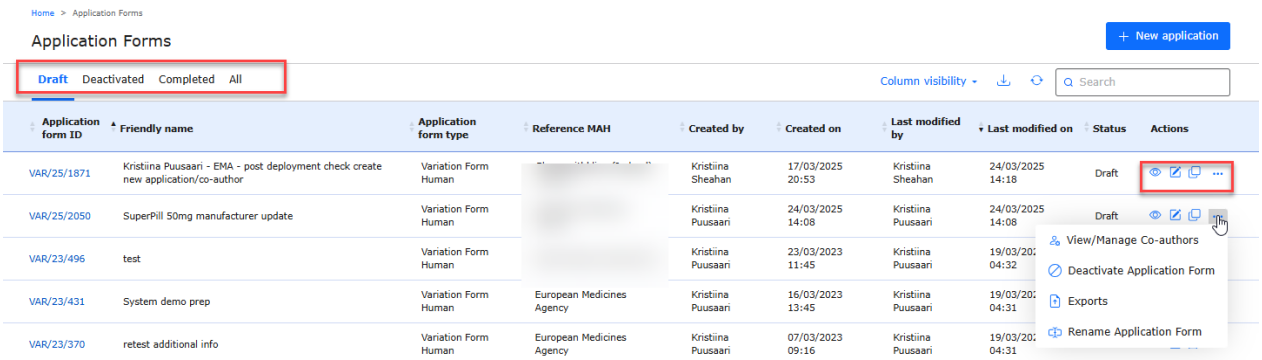


Figure 16 - List of Application Forms

The Application Form(s) are distributed into different tabs, mainly reflecting their possible different statuses: Drafted, Deactivated and Completed and a tab for All the Application Forms.

In all four tabs, you may use:

- *the Search bar to more quickly find the Application Form you may be looking for,*
- *the Column visibility button, to hide/unhide columns from the list of Application Form(s),*
- *the Refresh button, to get the latest list of Application Form(s),*
- *the Download button, to extract in Excel format, the list of Application Form(s) visible on a specific tab. Note that in order to download the full list you must first click the 'Load more' button, otherwise the export will only contain the submissions displayed on the screen at that moment, and,*

- *the Create New Application Form button to initiate a new Application Form.*

If you are a coordinator or you regularly work on lot of application forms, you might initially only see a short subset of previously created application forms. To see all previously created forms that you have access to, please click the Load more button.

Modified by/date: Please note that the modified by/date will change if **any user** does any action, such as save, this includes 'automated system actions', such as overnight system review of last edited date. If you wish not to change the modified by, do not click 'save' anywhere, just cancel to come out of the form.

As the options differ for application forms in the different tabs, click the 'three dots' button  , at the right hand-side of each row on the list of Application Form(s), to check which actions you can perform on that Application Form. Those actions also depend on your assigned access role(s)/permissions.

The following table provides an overview of which operations can be performed for each Application Form status and access user role:

Table 1 - Application Form operations

User Role name / Application Form Status/tab	**Industry user(s)**			**NCA user(s)**
	(UAT) eAF Applicant Contributor	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	(UAT) eAF Competent Authority User
Draft	- View Application Form - Edit Application Form - View/Manage Co-authors	- View Application Form - Edit Application Form - Exports - Deactivate Application Form - Clone Application Form - View/Manage Co-authors - Rename Application Form		
Deactivated	- View Application Form - View Co-authors	- View Application Form - View Co-authors - Exports - Clone Application Form - Reopen Application Form - Delete Application Form*		
Completed	- View Application Form - View Co-authors	- View Application Form - View Co-authors - Exports - Reopen Application Form - Clone Application Form - Deactivate Application Form		
All	Operations depend on the Status of the Application Form. Refer to the above operations and statuses			
*	Feature not yet developed			

Description of the different operations:

- *Exports – export generates a PDF eAF document which contains an FHIR XML attachment,*
- *View Co-authors (available in the 'Deactivated and Completed tabs) – provides a (read-only) list of all previously added co-authors onto a given Application Form;*
- *View/Manage Co-authors (available in the 'Drafts tab) – displays a list of all previously added co-authors onto a given Application Form, allowing to manage that list (remove and/or notify co-authors) and to add new co-authors. If at least one co-author has been added, you may also remove yourself. In that case, you would lose access to that Application Form and would no longer be able to see/edit it.*
- *View Application Form (available in the Draft, Deactivated and Completed tabs) – provides a (read-only) view of the Application Form in terms of Product Selection, Type(s) of change(s), Procedural Information, Proposed Changes and Finalisation;*
- *Edit Application Form (available in the 'Drafts tab) – allows the user to edit all fields in that Application Form;*
- *Clone Application – creates a separate copy of the selected Application Form;*
- *Deactivate Application Form (available in Draft and Completed tabs) – updates the Application Form status to Deactivated. Marking Application Form with the Deactivated status works as an intermediate **soft deletion** – deactivated Application Forms can always be moved back to Draft status, edited, finalised, and get Completed status or, once the functionality is available be completely deleted. Application Forms with Deactivated status have a retention time of one year – after that time, if the Application Form creator does not reopen or finalise it, that Application Form will be **completely** deleted. A notification e-mail will be sent to the Application Form creator seven days before the end of the retention period;*
- *Reopen Application Form (available in Deactivated and Completed tabs) – updates the Application Form status to Draft, allowing editing of that same Application Form;*
- *Delete Application Form – it completely deletes the Application Form so that it will no longer be possible to see/access it. Note: this feature is **not** yet **available** and while it will be a useful function, the development has been postponed to further into future as the 'deactivate application form' function can be used as a 'soft delete' for the time being.*

Electronic Application Forms with the Draft or Completed status have a retention period of 104 weeks (approximately 2 years).

2.1.3.1. Re-open 'completed' or 'deactivated' form for further editing

If a VSI (validation comment) is requested by a regulator that leads to a need to edit already completed application form (a form that has been finalised (using the Finalisation function) and submitted to the regulator) it is recommended that a copy of the original form is created.

If you need to edit a form that has been finalised i.e. it is in the 'completed' tab, it can be reopened for editing by clicking the small arrow in the right-hand corner in the list of forms (completed tab). There might also be a need to re-open a deactivated form, this is done the same way, selecting the option 'Re-open application form'.

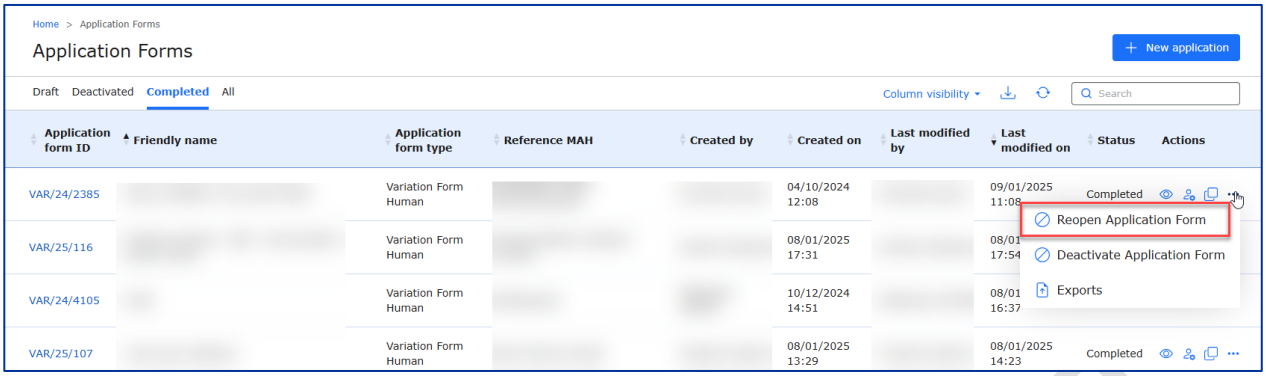


Figure 17 - Reopen Application Form

Upon clicking this option, the form in question moves back to the 'Draft' tab where the editing can be continued.

Once the editing has been completed, the form can be 'finalised' again and it will be moved back to the 'Completed' tab.

2.1.4. Clone application (also known as Copy application) function

The clone application (form) function creates a complete copy/clone of the selected previously created application form. The feature is available for all applications, regardless of the status of the form (draft, deactivated or completed).

When creating a copy, it is possible to change the MAH. If a different MAH is selected products are removed from the copy to avoid any unintentional sharing of commercially confidential product information.

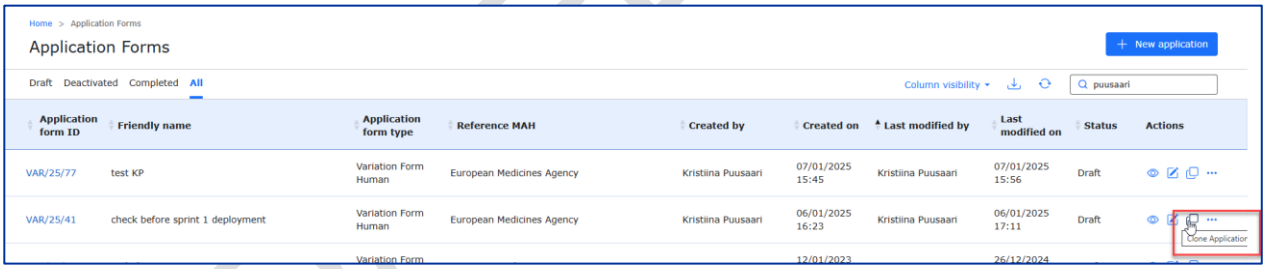


Figure 18 - Clone Application

Upon clicking the Copy application option, a new window will open where the user will need to give the form 'Friendly name' and select the MAH – follow the same steps as when you create a new application with filling in the application particulars.

This feature caters to two different scenarios:

1. The first scenario addresses situations where an application has been previously submitted, however subsequent requests for information or alterations have arisen. Users may want to retain the original, finalised version while making modifications for resubmission or to address queries. This functionality serves as **a solution for versioning**. It enables the creation of a clone of the original application, allowing modifications to be made, thus maintaining two distinct versions of the same application.

2. The second scenario pertains to **reuse of the application form particulars** and is comparable to **'save as'** which is very useful if you for example have another variation application containing all or some of the same products as in previous application.

Occasionally, it might be necessary to change Marketing Authorisation Holder (MAH) and access limitations might prevent the cloning of products, ensuring adherence to security protocols, and consequently, only other relevant information will be cloned.

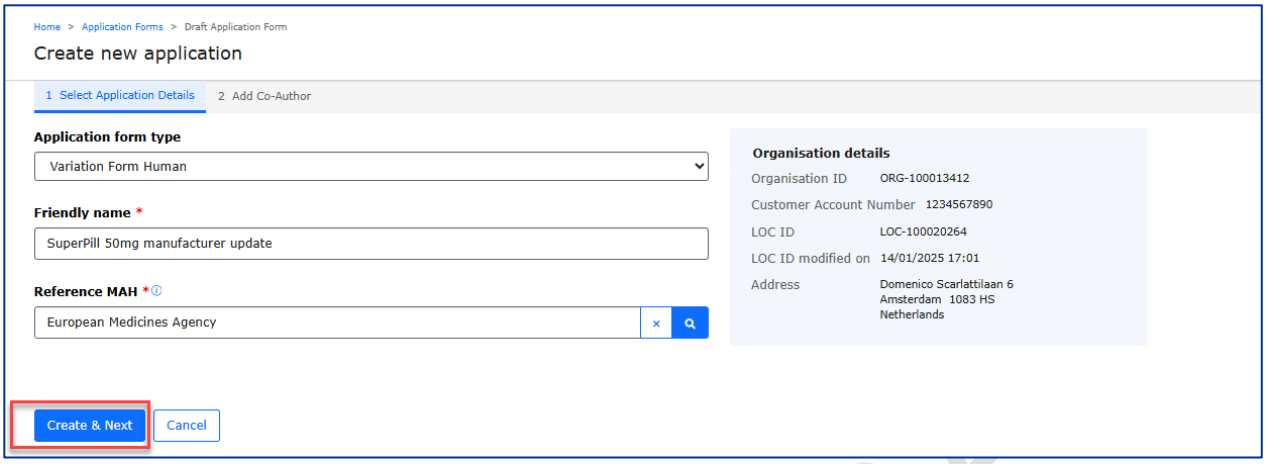


Figure 19 - Create & Next

- Upon selecting "Create and Next," the process involves recognising the user initiating the cloning procedure, possessing inherent access to the application. Within the organisation, individuals holding a coordinator role have overarching visibility into all applications, thus eliminating the necessity for explicit inclusion in this specific instance. If the organisation structure designates all country affiliates of headquarters as coordinators, sharing the clone directly with them becomes unnecessary. However, should a specific organisation in a particular country require access to the clone, the individual responsible for managing the application in that country can be added as a Co-Author using the "Add co-author" feature.

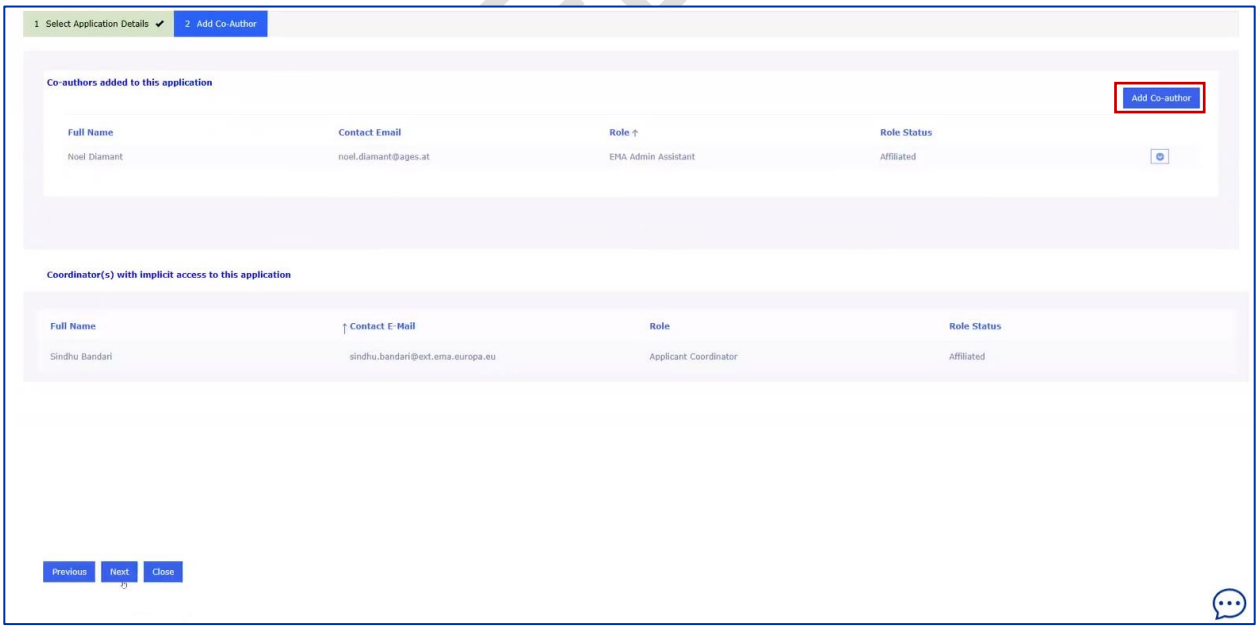


Figure 20 - Add Co-Author

- Upon completion of these setup configurations, click on the "Next" button to start a comprehensive duplication process. This includes replicating all previously entered data—such as products, scopes, and proposed changes—ensuring the transfer of all relevant information to the newly created clone.

IMPORTANT NOTE: *Please do not interrupt the cloning process by clicking 'close' in the 'Add Co-Author window, or return to the application list before the copying has finished. Although the 'Close' button is available here, please always click 'Next' instead to avoid errors in the copy. Interrupting the copying will lead to creation of an empty or partially cloned form and can cause further issues during the form editing. Please note that we are currently working on an improvement to prevent interruption of the copying process to prevent these issues in future.*

- While the copying is ongoing, a notification is placed on the screen to prevent editing until the copying has finished.

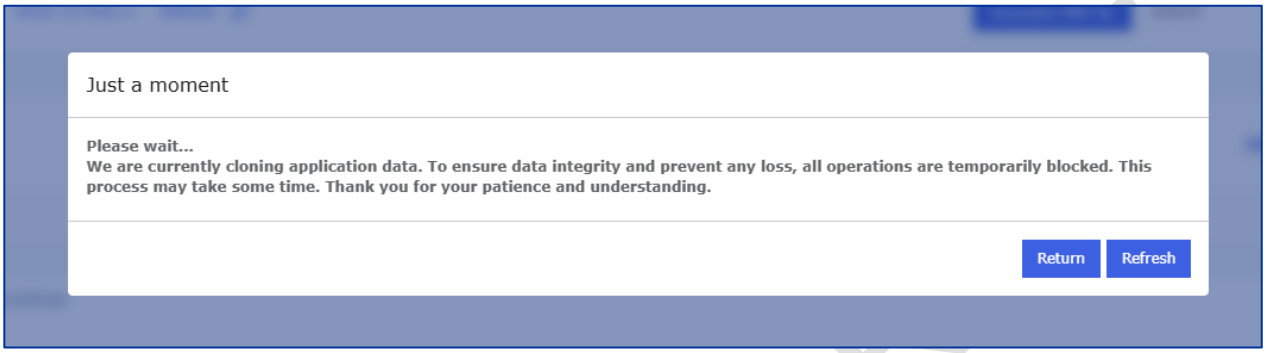


Figure 21 - Ongoing Cloning Application Data

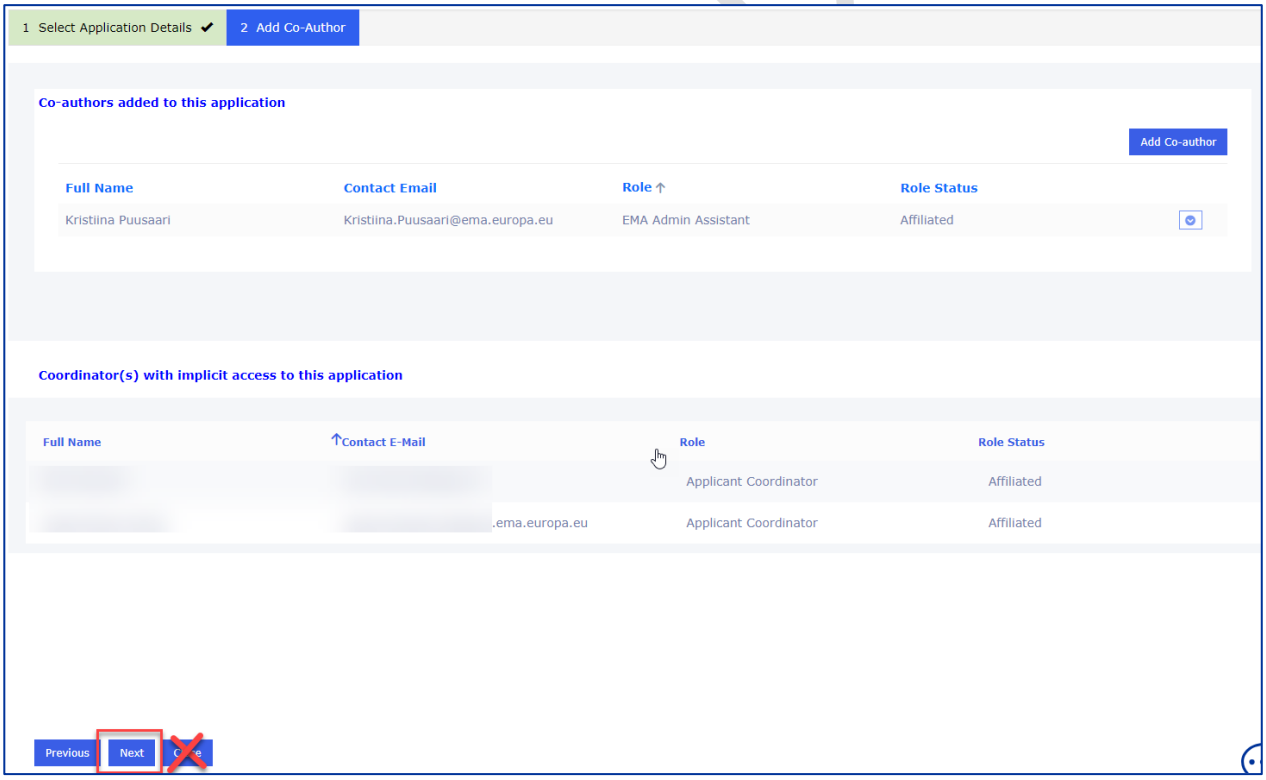


Figure 22 - Cloning Application "Next"

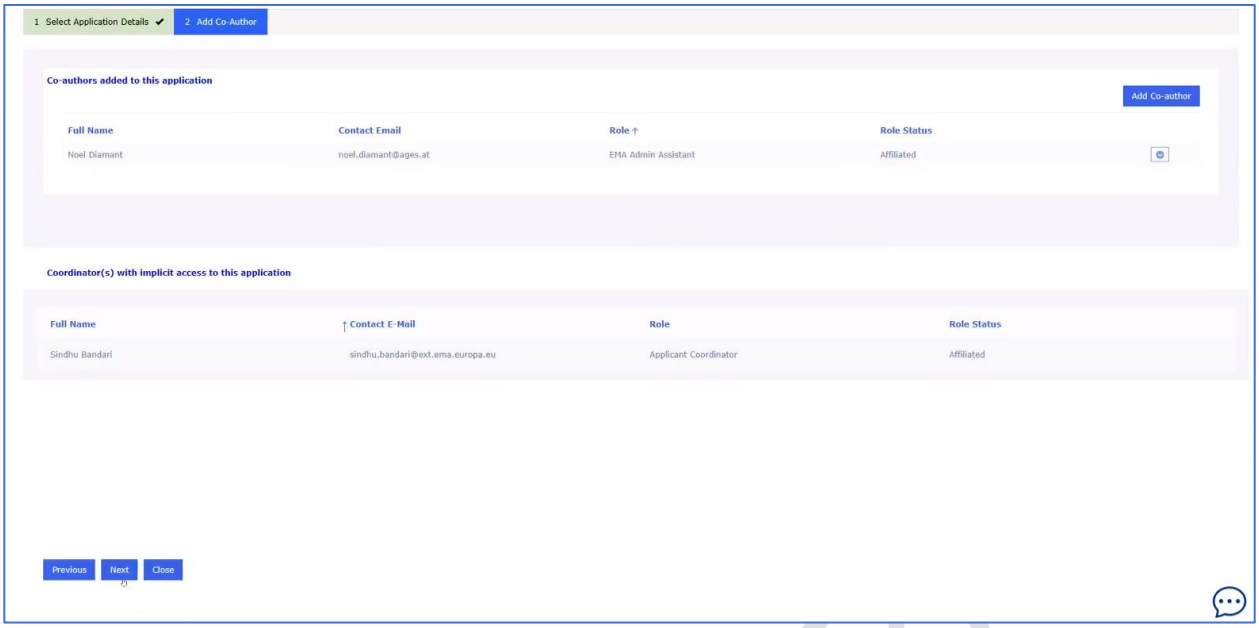


Figure 23 - Completed Cloning Application

The selected scope is cloned

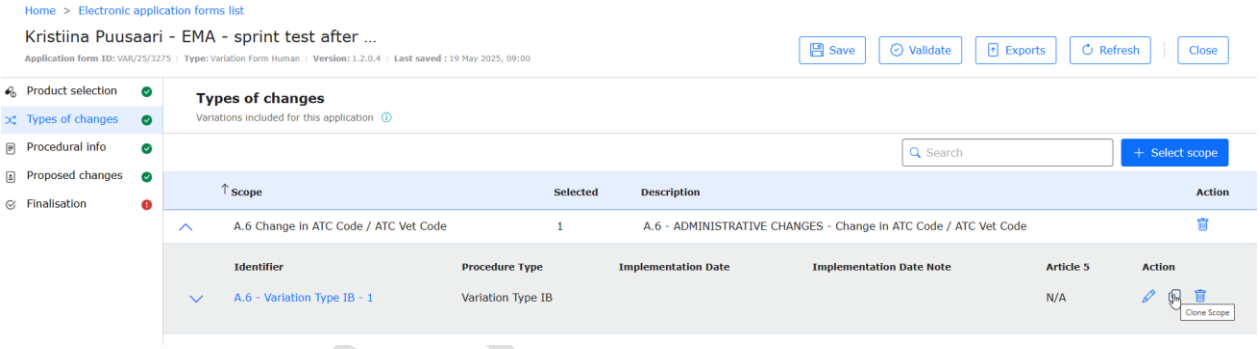


Figure 24 - Cloned Selected Scope

Procedural information will also all be cloned

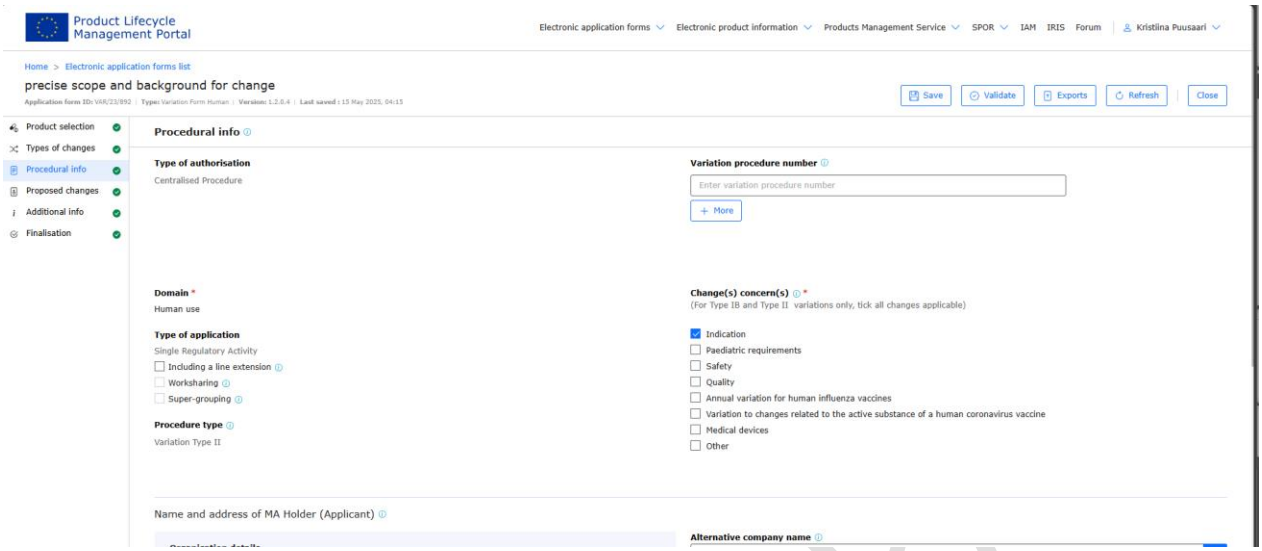


Figure 25 - Cloned Procedural Information

The form procedural information, including contact person contact details are copied

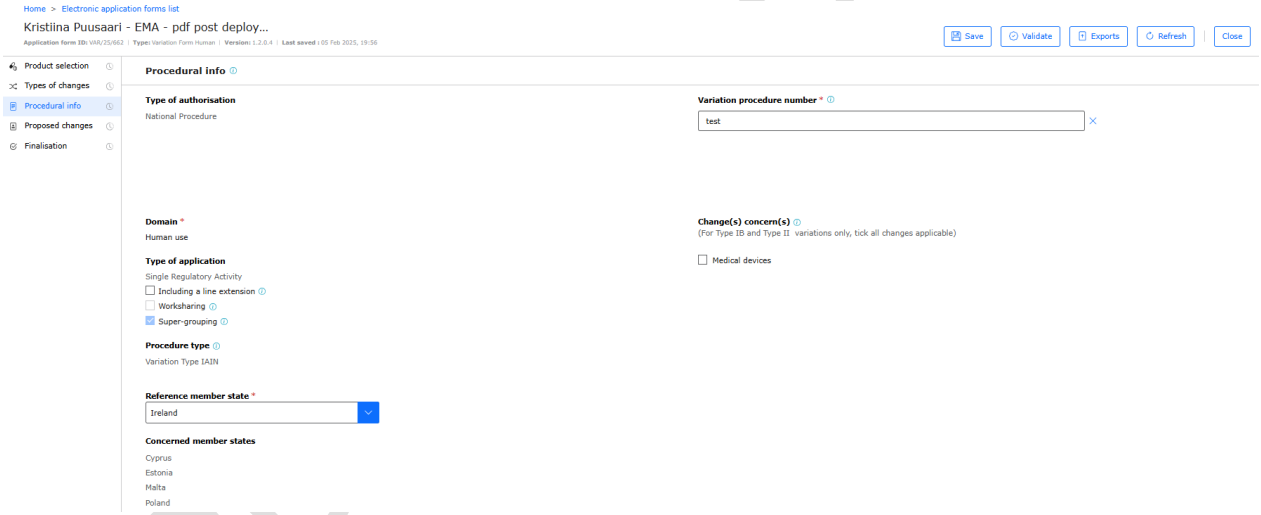


Figure 26 - Cloned Procedural Information with Contact Details

Within the "Proposed Changes" section, "Precise Scope" and "Background" are be cloned.

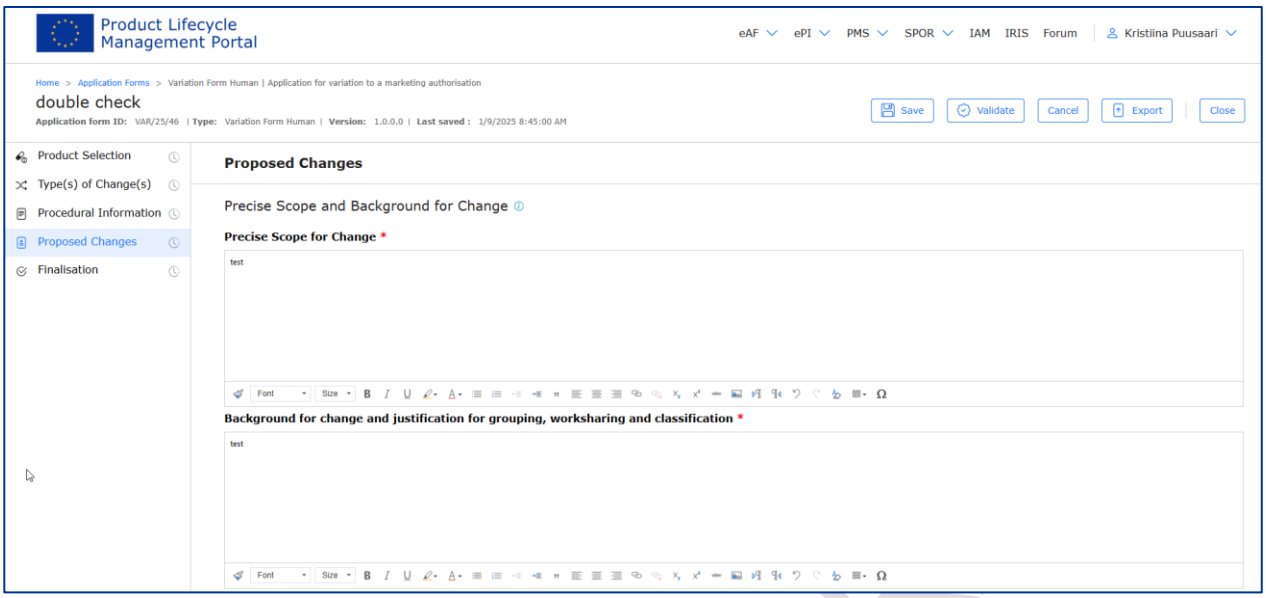


Figure 27 - "Precise Scope" and "Background" Cloned

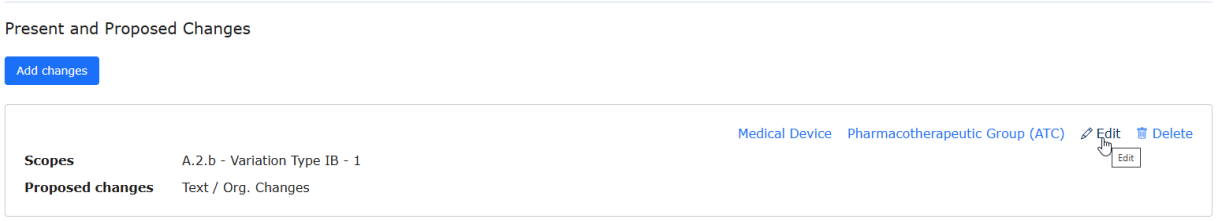


Figure 28 - Present and Proposed Changes

1. If you are cloning an application and have selected a different MAH, the product might not be available for you. Therefore, please access the product section and manually select the specific products pertinent to this application. Simply choose the relevant products and incorporate them into the application by utilising the "Save" button. Subsequently, **associate** the previously created present proposed texts **with these selected products** to ensure their alignment. For non-CAP products, all scopes are normally automatically associated to all non-CAP products, in cloned applications **you will currently need to re-associate the newly added products to the scopes** i.e. the scope tickbox needs to be re-ticked to ensure the scopes are selected.
2. Please note that any 'Other applications' that have been selected in the original application will also be cloned. If you are changing the product, **please manually delete** the previously selected procedure numbers related to other products. Please note that this is a bug which will be addressed in a future release.

2.1.5. Delete form function

The delete form function is **not** yet **available** and while it will be a useful function, the development has been postponed to further into future due to prioritisation of user stories and as the 'deactive application form' function can be used as a 'soft delete' for the time being.

2.1.6. How to add/delete co-authors from an Application Form

Industry users with the eAF Applicant Manager role or the eAF Applicant Coordinator role and NCA users with the eAF Competent Authority User role may add/delete co-authors from an Application Form.

You may add/delete co-authors either (i) at the time of creation of an Application Form, (ii) when copying an application form or (iii) at any other point in time, after having created the Application Form.

1. For (i), please follow the instructions on section 2.1.2 How to create a new electronic Application Form;
2. For (ii), please follow the instructions on section 2.1.3 How to access previously created/edited electronic Application Form(s)

2.1.7. Concurrent users

The system **does not** currently prevent multiple users accessing the same application form at the same time and there is **no indication** for the multiple users that another colleague is currently editing the same form. Concurrent edits can and in most cases will lead into **data loss** as the system will save changes entered by the person who 'saves' their changes first. Applicants are strongly advised to ensure through internal workflows that multiple colleagues are not working at the same time in the same application form to avoid data loss and/or systems errors.

2.2. Product Selection

2.2.1. How to add a product in an Application Form

2.2.1.1. Unfiltered view (adding products without searching)

Industry users with the eAF Applicant Manager role or the eAF Applicant Coordinator role and NCA users with the eAF Competent Authority User role may add/delete products from an Application Form.

It is recommended that the form is filled out in the order the sections appear in the PLM Portal web user interface. The automations and calculations will work in an optimum way when the steps are followed in the proposed order. It is of course possible to move back and forth between the different sections, however, some changes in selections may not be immediately reflected in the form, or may not be reflected upon until the 'validate' button is clicked or the form is refreshed.

IMPORTANT NOTE: The list of displayed products strongly relates to roles that have been granted to your user account - **you will only be able to see the products that are authorised for the organisation in which you have the Applicant Manager and/or the Applicant Coordinator roles**.

The **adding of products** should always be the first step when starting to fill in the web-based Application form. Refer to the Products Selection step on the left-hand side of the menu.

1. Access an existing form from the applications list or create a new Application Form. See sections 2.1.2 and 2.1.3 for further details
2. In the Product Selection page, as a first step in a new application form click on + Select Product button.

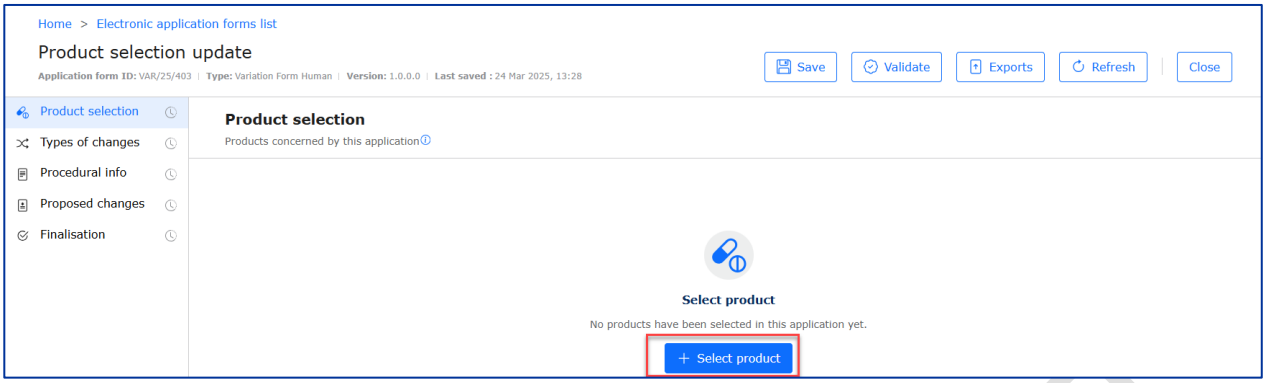


Figure 29 - Add Product

3. Upon clicking this button, **an empty search grid will appear**. If you wish to see **all products that are available to you**, you need to click the **magnifying glass** icon on the left-hand side of the search grid. If you know that you have more than 10 products available for you and you wish see an extended list, you need to, as the first step, change the number of products shown to you by clicking the Show 10 rows button before clicking the magnifying glass. The default view is limited to 10 products.

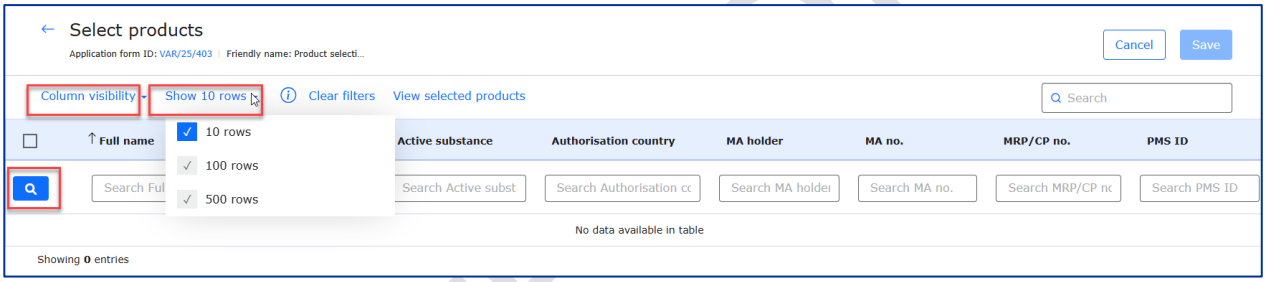


Figure 30 - Column Visibility

4. The unfiltered view will simply give you the first 10 (or 100 or 500 if you manually change this) products available for selection. If you have more than 500 medicinal products available for selection, you need to use the column filters to find the products you wish to select. Please note that you will only have option to select from medicinal products for which you are **affiliated** to, you will not see products from other companies unless you are affiliated to these other organisations.

5. Select the products by clicking anywhere in the row.

IMPORTANT NOTE: To improve system performance the product selection has been limited to 'saving' of up to 50 products **at the time.** If you need to select more than 50 products in the application form, you can simply repeat the product selection step as many times as needed. If you have used the 'select all' tickbox to select more than 50 products, you will not be able to save all the selected products. You will need to either cancel the function or manually deselect the products you save 'as the next batch' into the form.

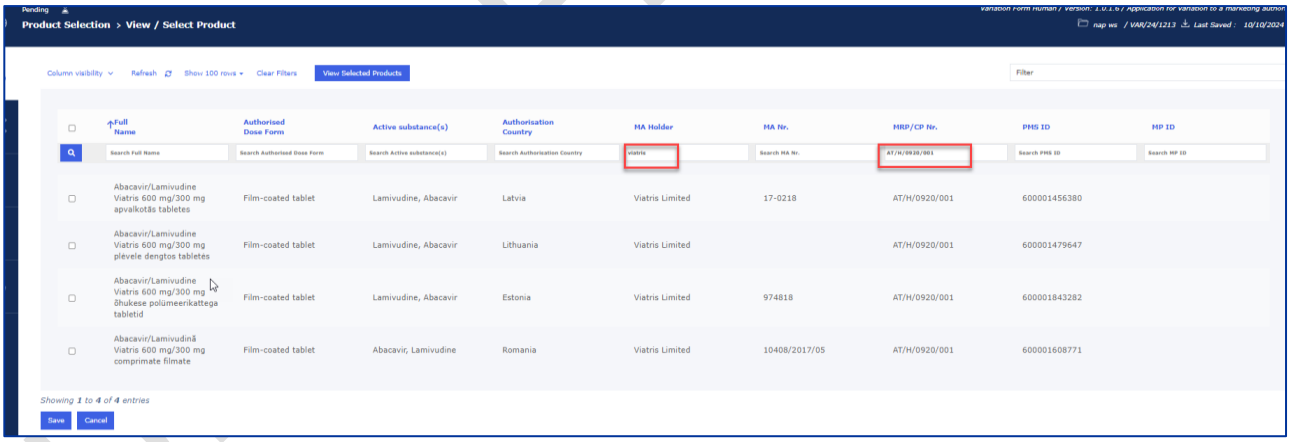
Figure 31 - Selecting the Product

2.2.1.2. Searching and filtering (adding products using search and filter options)

1. If your access gives you option to select from many products, it is helpful to use the search and filtering options to by using the search and filter capabilities you can find the required medicinal product(s) more quickly. Also, if you have more than 500 medicinal products available you will **need** to use the filters to find the relevant product(s). You can use one or more column filters. It is also possible to sort the columns by clicking the column name.

2. In the Select Product subpage, use available fields for defining the product search to select the applicable product(s). Different columns are available to allow users to select their preferred search criteria. It is possible to adjust the column visibility using the 'column visibility' option. Depending on the number of products available for each user the list may need to be filtered with multiple attributes. Please note that especially for products authorised through MRP/DCP or NP some attributes may be empty due to data issues or due to information not being available at that level, for example if the products are authorised on the packaged medicinal product level in the member state, there maybe not be a MA number available on the medicinal product level.

3. Start the search by typing into any of the search fields and click '**enter'** to start the search or click the magnifying glass to the left of the search filters.



4. It is possible to filter this list to look for the specific product(s) for selection using the field called 'Filter'. The more you type the more the list is filtered.

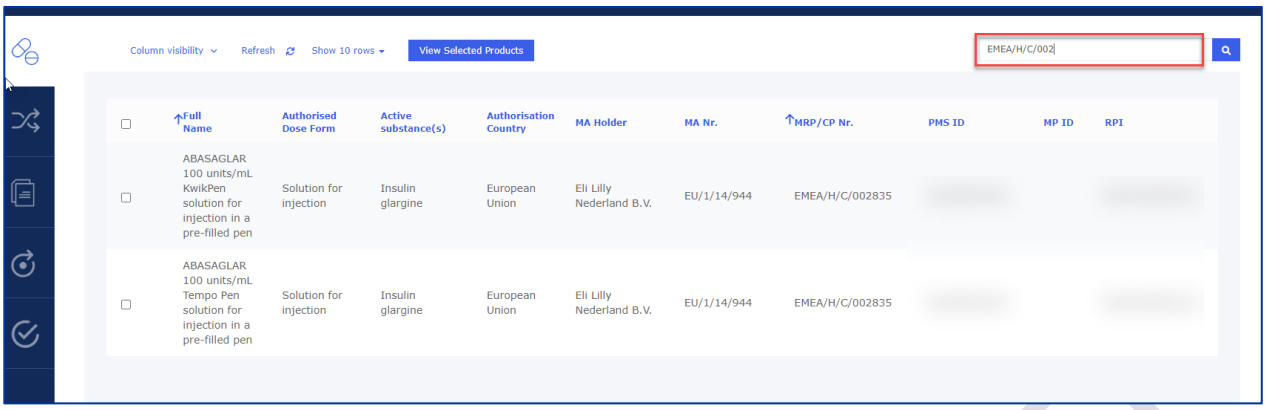


Figure 32 - List of Products

5. When you have found the products you wish to include in the form, please select the rows by clicking to them. It is not necessary to tick the tick box, selection can be done **clicking anywhere in the row**. Once you have selected the required products (maximum of 50 medicinal products can be saved at any one time), click save at the bottom of the page. If you need to include more than 50 products in the application, please repeat the select and save as many times as needed selecting maximum of 50 products at the time.

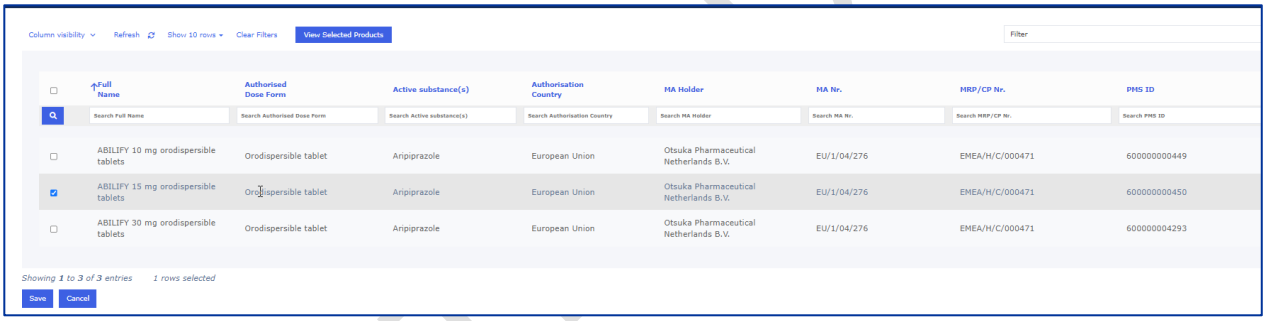


Figure 33 - Including Products in the Form

NOTE: the product selection works better if you simply **click anywhere on the row**, for example near the product name, rather than attempting to tick the available tick box. You may want to use the search bar to further **filter** your displayed products list.

6. Click on the Save button.

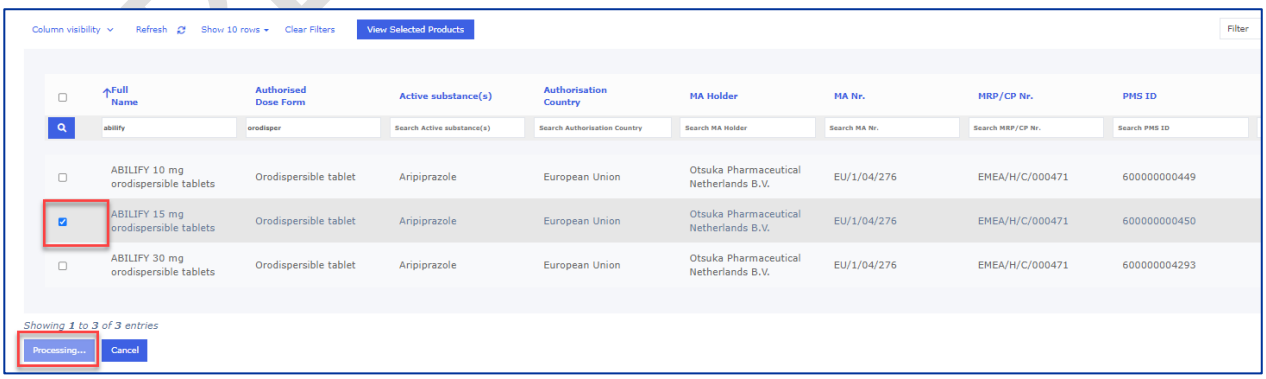


Figure 34 - Saving

Please note: After clicking on the "Save" button, the system will perform several adjustments and integration in the background while the product and related packages are added to the application form. While these 'background maintenance' activities are happening, editing the form is blocked by a maintenance pop up window. Please note that the duration that further actions on the form are blocked by the pop up depends on the number of selected medicinal products and the number of available packages for those medicinal products. Saving of products is limited to 50 medicinal products at one time. The selection of products and saving of them can be repeated as many times as needed.

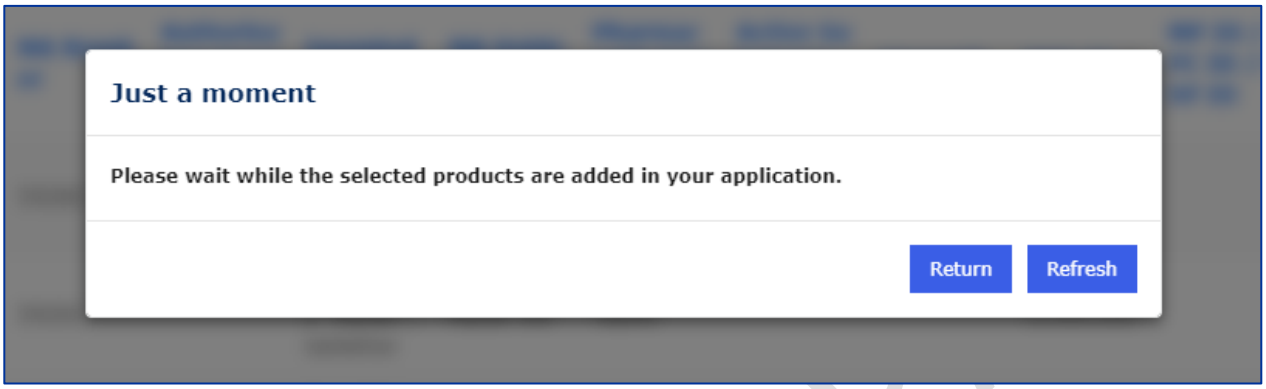


Figure 35 - Adding Products in the Application

7. The message will remain on the screen until the background processes have finished. The "Return" button will redirect the user to the **application form list**, and the "Refresh" button will refresh the current page.

8. Once the pop up disappears, you are presented with a list of your selected products. You can click the arrow on the left side of the Medicinal Product name to expand to view the list packaged medicinal products.

   Please note that the packages impacted by this variation are selected in the Present and Proposed section. **All packages appear unselected** until they have been selected in Present and Proposed section. **For CAPs only** it is possible to **select only packages that are impacted by the variation**. Also, for CAPs only, it is possible to indicate which packages are impacted by which classification scope.

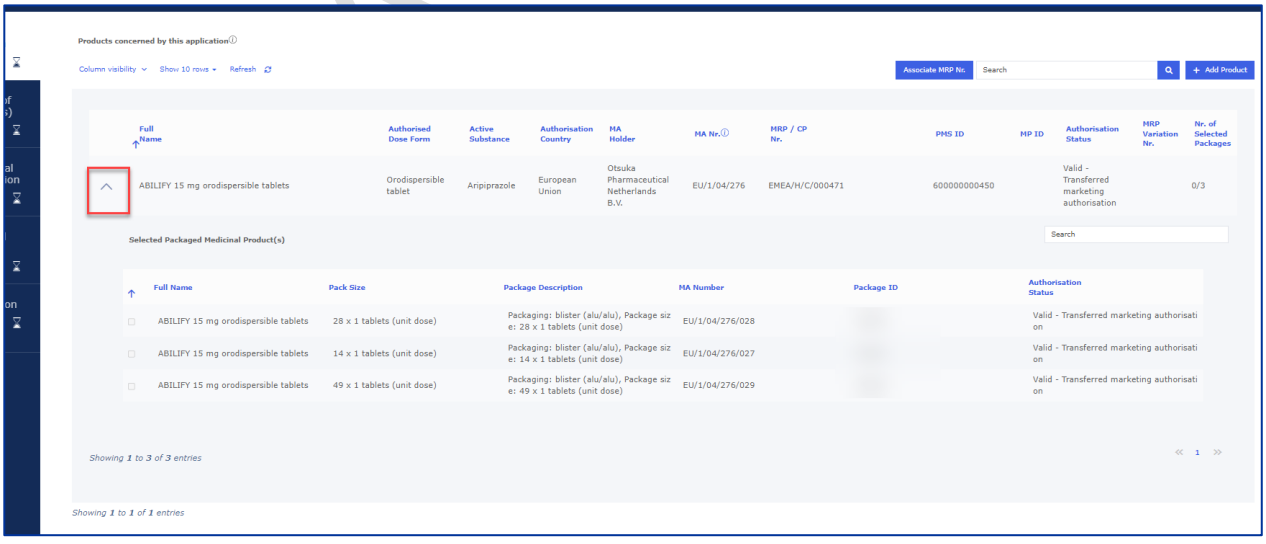


Figure 36 - Expanding view of List Packaged Medicinal products

9. If you wish to add more products, please repeat the steps above, however, please note to improve performance we have limited the saving of the products to 50 medicinal products at the time. The product selection process works like a 'shopping basket' function where you select the product by ticking the box and you can clear filters and launch new searches until you have selected all products you need, and then click save.

For very large applications containing several hundreds of medicinal products, we are aware of intermitted issues. The implementation of saving of limited number of products guarantees the correct functioning of the saving of the products in the application form and hence helps the overall performance although it can feel like a limitation at first. Viewing selected products

If you are in the middle of adding products to the form and wish to view products that have been already added to the form you can click on View Selected Products to have a glance at the products you have selected and saved previously. You can toggle between that view and the View Available Products view to go back to the full list of selectable products.

Please note that the list of available products will only become visible once at least one search criteria has been added to the search grid. Otherwise, an empty search grid will be displayed.

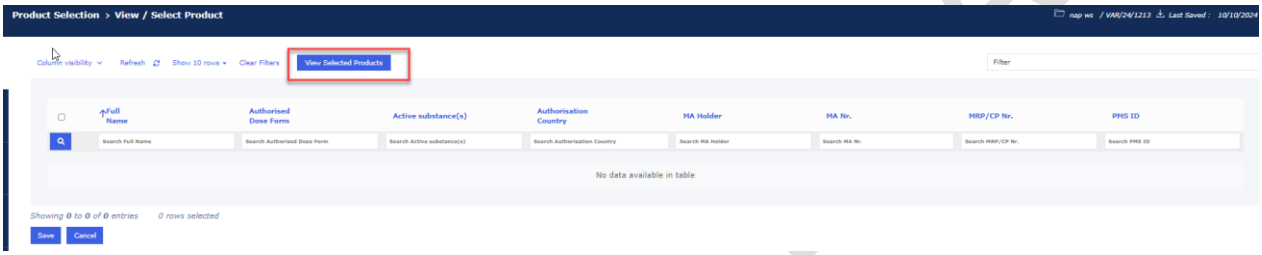


Figure 37 - View selected products

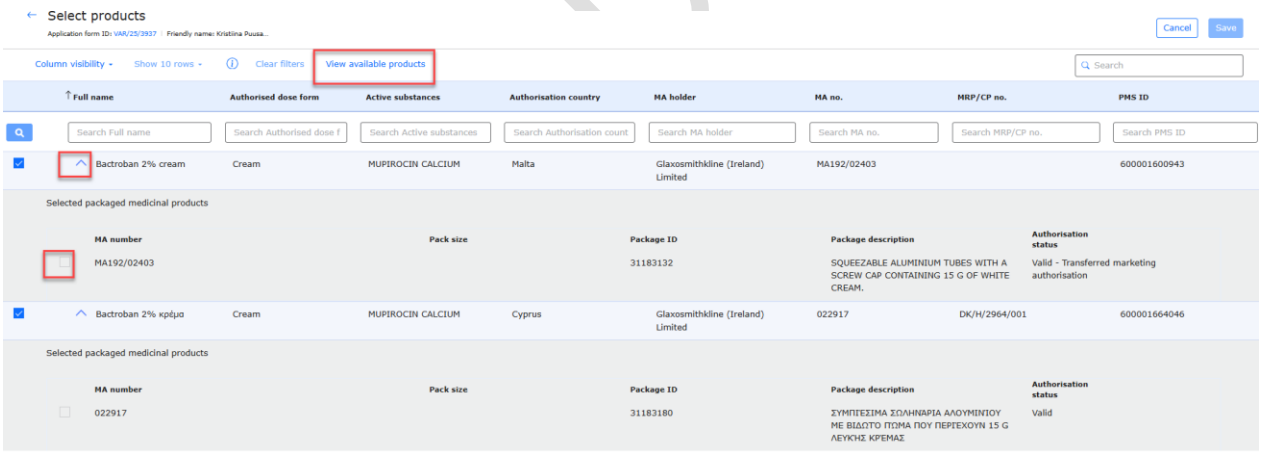


Figure 38 - View Available Products

If you do not find the product(s) you are intending to select, click on the Refresh button and try to define the search criteria. Otherwise, please double check your roles. The product could also be associated with another MAH. You can check the full product list in the 'SPOR' menu by selecting the Medicinal Products option. Here you will be able to view a Human Medicinal Product Overview report which can be filtered and viewed.

You may also edit the columns that are displayed in the screen. Click on the Column visibility button to select/unselect the intended columns to be displayed.

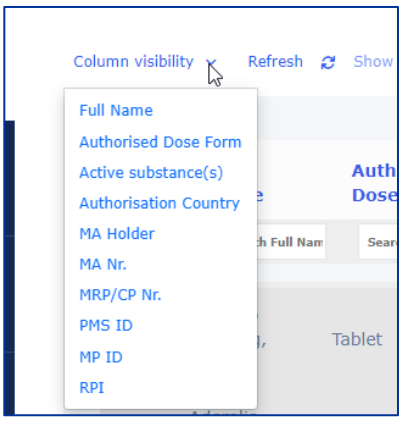


Figure 39 - Column Visibility

Once the background activities have finished, the list of selected product(s) is displayed and, you may view the presentations of the selected products. You can do this by clicking the small 'arrow down' on the left-hand side to the product name field. This arrow will expand the accordion to show the 'Selected Packaged Medicinal Product(s) i.e. the presentations available for each selected medicinal product. **Please note** that you **cannot** select the presentations in this view, you can simply **view** them. The linking of the packaged medicinal product and the scope is done in the Proposed Changes section (Present and Proposed).

Please note: in some cases there may be a **delay** in the display of the packaged medicinal products in this view. You may have to wait for several minutes for the view to be refreshed so that you can see the presentations. You can see if the view has refreshed when you can see the 'number of selected packages' column to display the number of the packages for each medicinal product in the last column.

If the number of packages in this column is 0/0, it is possible that there is a data error in PMS. If you experience this, please raise a service desk ticket to report a problem with a product.

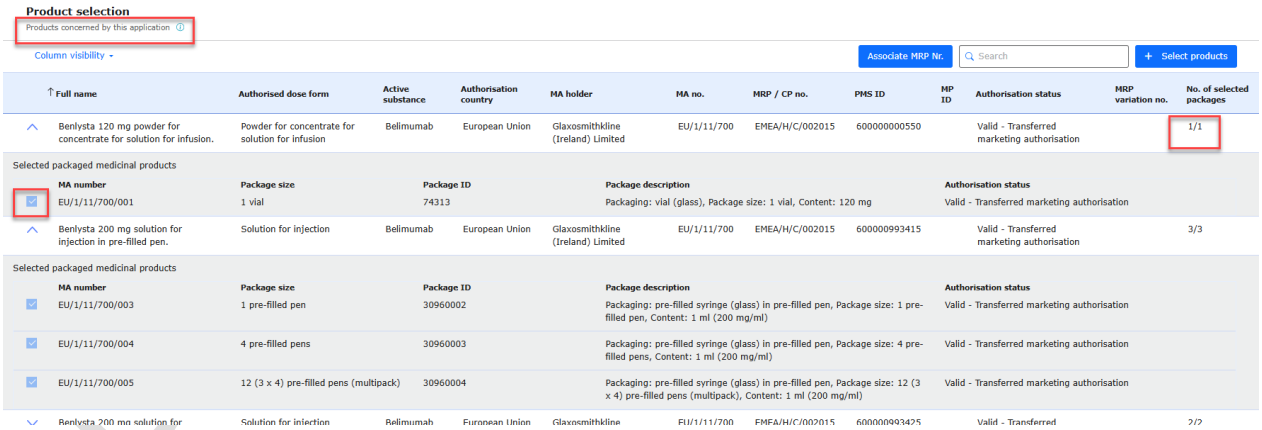


Figure 40 - Packaged Medicinal Product(s)

This view may also be particularly useful if you have multiple medicinal products that have the same 'Full name' but your variation only concerns one of those medicinal products (you may have a difficulty to identify which medicinal product to select in product selection page and you may wish to add both/all and then come to this view to see which medicinal product contains the presentations you wish to select). To remove already selected medicinal product that should not be included in the application form, please click the 'Add product' button again and deselect (by clicking the row(s)) the selected products not needed in this application and save the updated selection.

Please note that in this view, you **cannot** unselect any presentations. They all appear selected also for CAPs. If you wish to associate only selected packages with selected scopes, you will need to do this at the 'Present and Proposed section.

Back in the Product Selection page, click on the Save button. You may want to click on the Validate button to change the status of this section to Completed. Please note that you cannot validate until the packaged medicinal products have been 'calculated' and the number of packages has updated in the last column.

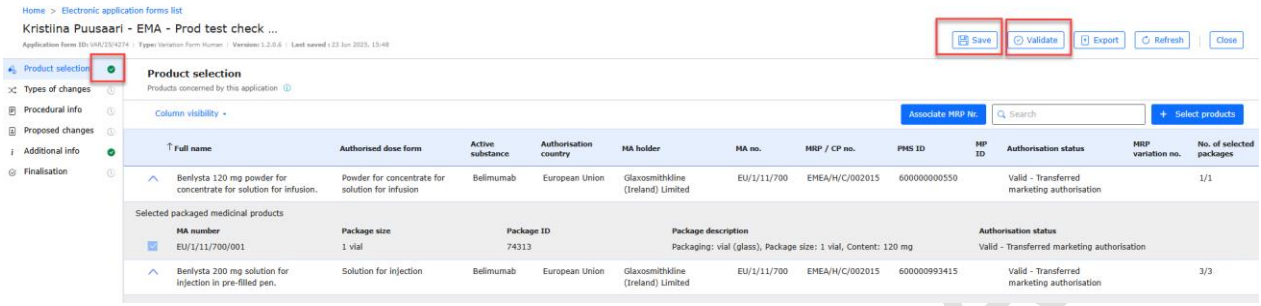


Figure 41 - Save and Validate Buttons

2.2.1.3. How to update the MRP Nr. of a product in an Application Form

DISCLAIMER: the Associate MRP Nr. feature applies to WS variations containing CAPs and non-CAPs and for variations containing non-CAPs only. It is now possible to indicate the MRP number for purely National Products. This feature **cannot** be used for CAP only variations.

NOTE: It is a **mandatory** step to add the MRP variation number **for all MRP/DCP products** – if this is not done, the products are **not shown** in the section 2 of exported pdf form.

1. Access an existing or create a new Application Form. See sections 2.1.2and 2.1.3 for further details
2. Once you have selected the products you wish to add in to your application form, on the Product Selection page, click on the Associate MRP Nr. button

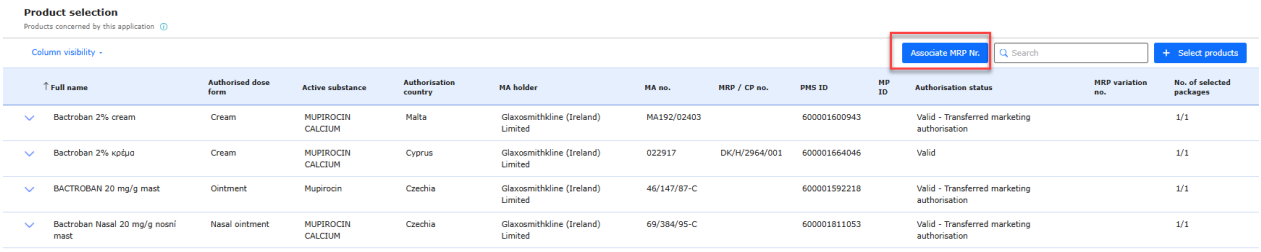
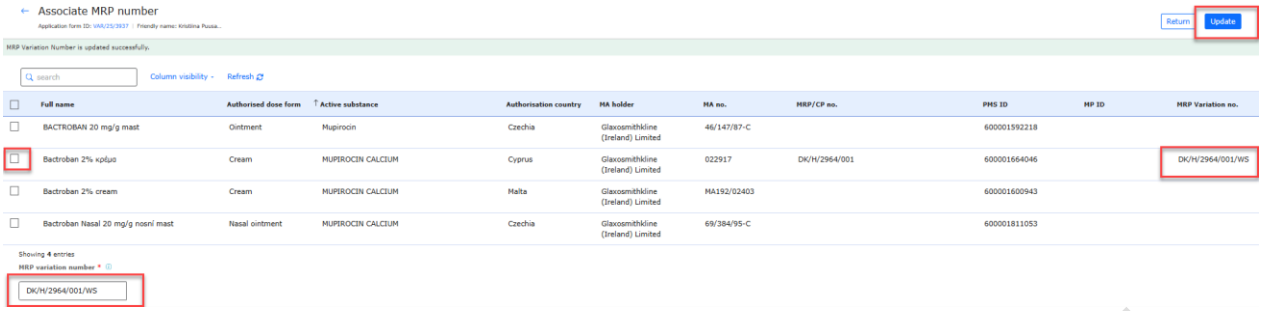


Figure 42 - Associate MRP Nr. Button

3. You will see a list of MRP/DCP and purely national products you selected in a previous step. You must add the MRP Variation number for the relevant MRP/DCP products in the field called MRP Variation Number and select, by clicking the row, the relevant product(s). It is now also possible to indicate the MRP number or a purely national product. Once you have finished selecting the product(s), press the Update button. Repeat the step to add the relevant MRP variation number to each respective product.



4. Once you have finished, click the Return button and you will see the list of products with the added MRP numbers.

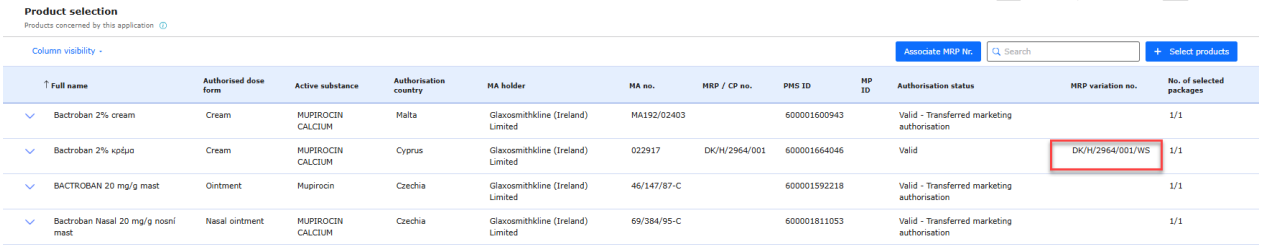


Figure 43 - MRP Numbers

5. The variation procedure number will be reflected in the relevant field of section 2 of the exported pdf eAF

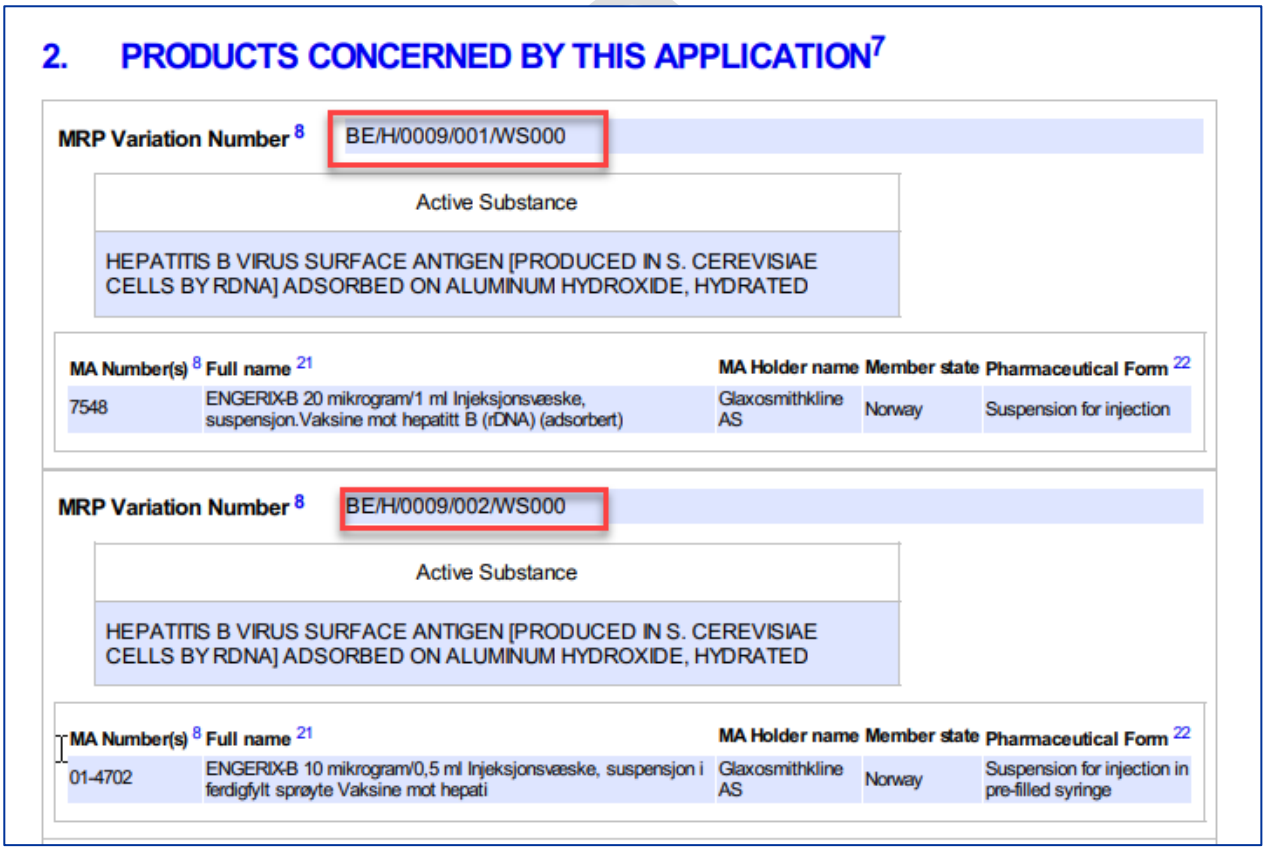


Figure 44 - MRP Variation Number

2.2.1.4. How to delete a product from an Application Form

Deleting a product from an Application Form implies to have added at least one product to that same Application Form beforehand. See 2.2.1 on how to add a product.

1. Access an existing or create a new Application Form. See sections, 2.1.2and 2.1.3 for further details
2. In the Product Selection page, click on + Select products

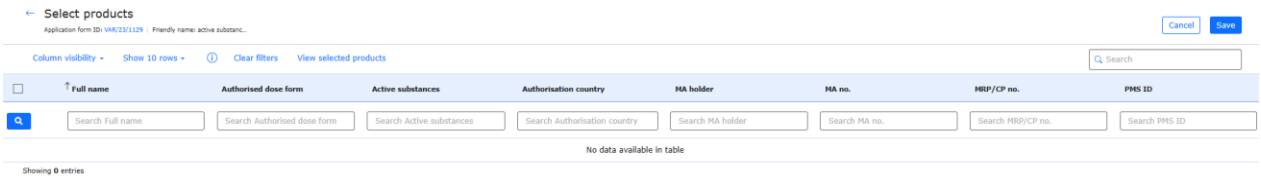


Figure 45 - Add Product

3. Click on View Selected Products to have a glance at the products you have selected and saved in your application previously. You may switch between that view and the View Available Products view to go back to the full list of selectable products.
4. In the Select Product subpage, un-tick the product(s) click the View Selected Products button and on the list of selected products, you will be able to remove/delete products from the application form (click anywhere in the line). You may want to use the filters or the filtering field to further define your displayed products list.

   Note that the list displayed products strongly relates to roles that have been granted to your user account - you will be able to see the products that are authorised for the organisation in which you have the Applicant Manager and/or the Applicant Coordinator roles.

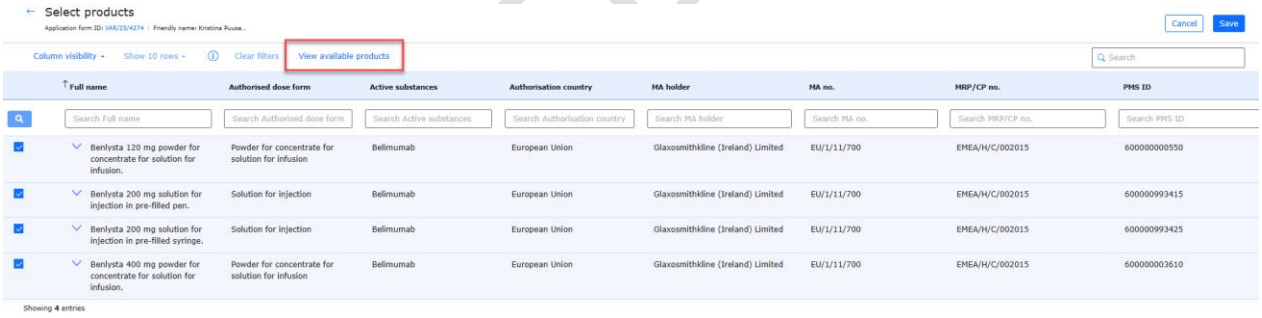


Figure 46 - View Available Products

5. Click on the Save button to ensure that you save the changes you made i.e. to save the deletion/addition of any other products.
6. Back in the Product Selection page you can see the updated list of products. You may want to click on the Validate button to change the status of this section to Completed.

NOTE: even though it is possible to see the list of Packaged Medicinal Products (i.e. the presentations) after selecting and saving the products, it is **not** possible (**as per design**) to be able to **select** or **unselect** the presentations at this step. The list of presentations is displayed to ensure that the applicant can review, and ensure that they have selected all correct medicinal products. The **selection of presentations** impacted will be done at the time when products and scopes are linked in the **Proposed Changes** (Present and Proposed) section.

The packaged medicinal products, **linked to the variation scopes** in Present and Proposed section are those that will be **displayed in the section 2** of the **pdf** export.

For CAPs only, **the presentations that have not been linked to any variation scopes will not be listed in section 2** and are **not included** in the variation procedure. It is **very important** to check and confirm that **only** the relevant packaged medicinal products (i.e. presentations) are linked to variation scopes to avoid unintentional changes to presentations that are not impacted by the variation.

For non-CAP products, where the authorisation is on the medicinal product level, **all presentations of the medicinal product are always automatically selected** and cannot be unselected.

Known limitations:

There are number of known limitations in the system at the moment, some related to product data quality, some related to functional issues/limitations/bugs. Please see a subset of these issues listed below:

- The search should be triggered with press of 'enter' however, it is not always responsive and you may need to click the magnifying glass on the left side of the search grid
- There are number of various data quality issues in the system, for some we are currently working on technical solutions, some are due to the data quality from eXVMPD. Here, some examples of known data issues;
    - Products authorised in **Finland** are submitted to xEVMPD with both, the Finnish name and the Swedish language name. While the issue has been corrected for majority of the products authorised in Finland, the system still occasionally, displays one of these products with the product name in Swedish language. In most cases where this happens, only Swedish name is available in PMS. If you notice that the Finnish language entry is missing for your product, please check that the Finnish name is available in xEVMPD. If xEVMPD is correct, please raise a PMS ticket and the issue will be investigated. .
    - Products authorised in **Belgium** have similar issue, however, they appear **randomly** with either Flemish, French or German language name. We are still looking for solution to ensure that the products can be searched with the 'correct' name.
    - **Corrupted** products (affecting CAPs and non-CAPs) – small number of corrupted products (i.e. products that are not available for selection are still listed and visible in the eAF, however, upon selection they cause an error in the form. Unfortunately we are not able to provide a list of such nullified products at this time as the list changes. The PMS team is currently working to fix the issue . If you have selected one of these corrupted products and are unable to export the pdf, please raise a service desk ticket and we might be able to fix the product in the backend.
    - **Duplicate** products (affecting CAPs and non-CAPs): due to data errors coming from xEVMPD/PMS some packaged medicinal products are currently visible under 2 different medicinal products. This will cause an error in the eAF and user will not be able to continue the use of the web based eAF until this data error is corrected. If you are preparing an eAF and experience this issue, please **raise service desk ticket** using the EMA service now, however it is most likely that we will ask you to use the interactive pdf eAF at these cases,

it is still important that these findings are reported so that we can ensure that the issue is thoroughly fixed.

- **Missing** products (affecting only non-CAPs (approx. 19000 products, where the authorised dose form is coming from a specific list e.g. combined dose form. Will not happen for example for simple dose forms such as tablets): due to data errors coming from xEVMPD/PMS some medicinal products are currently completely missing from PMS and hence they are not available in the PLM Portal eAF. Unfortunately, there is a large number of these products and user will not be able to use of the web based eAF for variations for these products until this data error is corrected. If you are preparing an eAF and experience this issue, please **raise service desk ticket** using the EMA service now so we can check if the product is impacted by this issue or there is another reason for it not being displayed. For missing products you will need to use the interactive pdf eAF.
-

2.3. *Type(s) of change(s)*

2.3.1. How to add a variation scope (classification category) in an Application

Industry users with the eAF Applicant Manager role or the eAF Applicant Coordinator role and NCA users with the eAF Competent Authority User role may add/delete scopes in an Application Form.

The insertion of scopes is logically the next step when filling in the web form. The selection of the scopes in the web form is comparable to filling in the first part of section 3 of the interactive pdf variation eAF.

Refer to the Type(s) of Change(s) Selection step on the left-hand side of the menu.

1. Access an existing or create a new Application Form. See sections 2.1.2and 2.1.3 for further details
2. In the Type(s) of Change(s) page, click on Select Scope

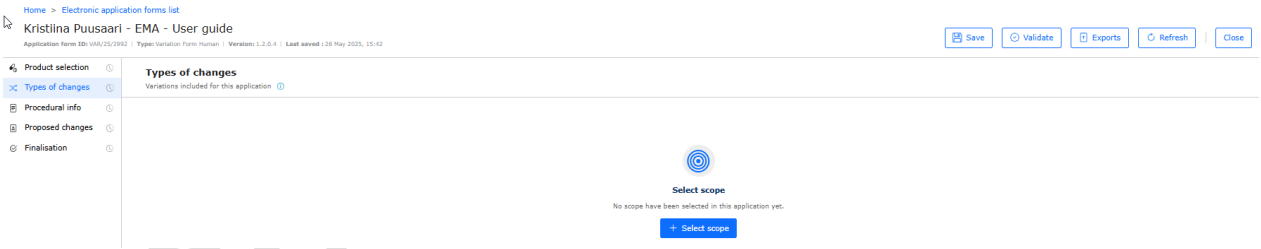


Figure 47 - Select Scope

3. In the Select/Edit Scope subpage, launch the search for scope (variation classification category) selection by clicking on the magnifying glass . The scopes (categories) cannot be searched in Select/Edit scope subpage. Clicking the magnifying glass will open the 'Select scope window where you can select the scope by filtering the list.

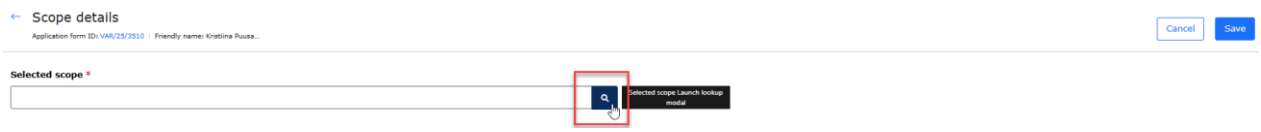


Figure 48 - Select Scope

4. In the 'Select Scope' window you will be presented a list of scopes with multiple pages to navigate to. The **easiest and quickest** way to select the scope is by **typing** the scope in the search field.

The more you type, the further the list will be filtered making it easier to select the correct scope (the list is not auto filtered, you will need to **click enter** or the magnifying glass to filter further). Please **note** that the search is **not** case sensitive, i.e. you do not need to use capital letters. Please note use of **roman** numbers where relevant (for example to search for C.I.6, you will need to type c.i.6, not c.1.6). If you wish to search using the 'text' part of the scope, please note that you need to add an asterix (*) as the leading character (e.g. *atc or *change..). Please note however, that search using the classification code is the fastest and easiest way to select the variation classification code (e.g. B.II.b.2.a type b.ii.b.2.a). In principle there is no change to the scope selection from the interactive pdf form where you drilled down the list of scopes by first selecting for example B, then I, then b etc. now, you do not need to drill down, but can simply type as many characters of the scope of change (classification code) you wish to select.

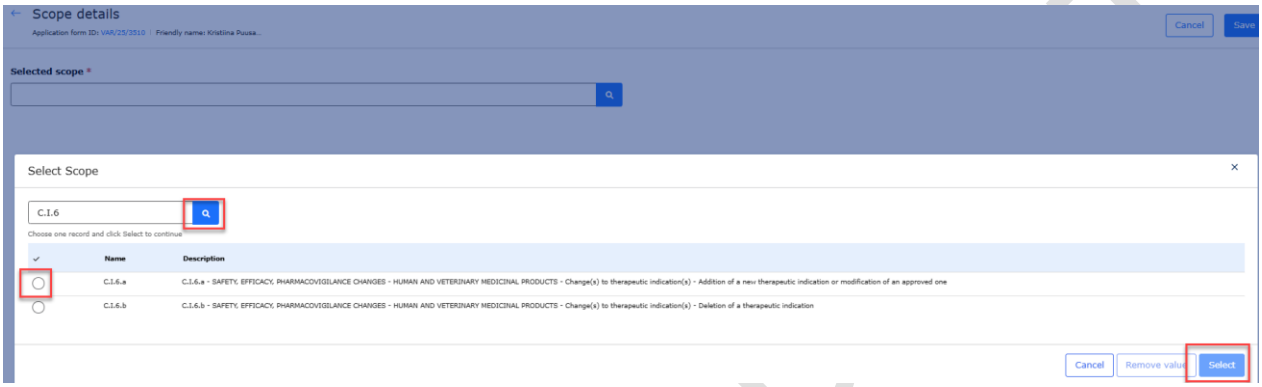


Figure 49 - Example of Search using Classification Code

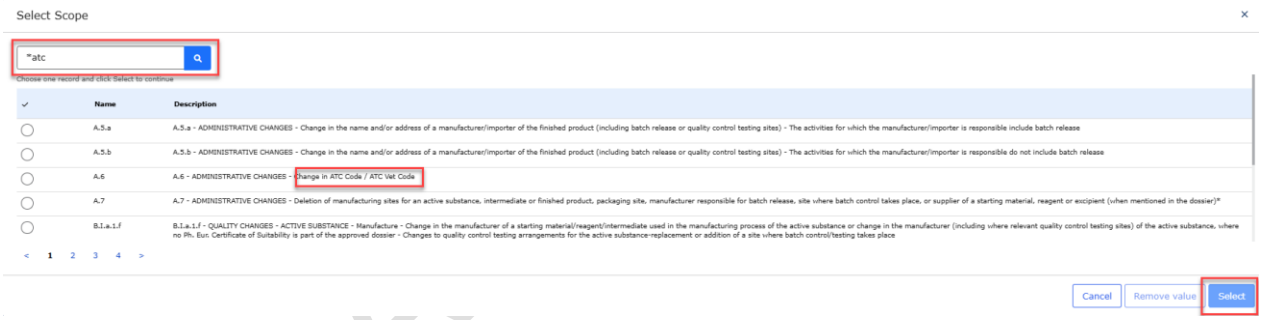


Figure 50 - Example of Search using Wild Card and Text

5. Select the needed classification code (scope), this is easily done by simply clicking anywhere in the row, it is **not** necessary to use the tick box, this will be ticked when you click anywhere on the row. Please note that you can only select **one scope at the time**.
6. Click on the Select button. If you wish to cancel and not select any scopes, click on the Cancel button

   Upon clicking the Select button you will be taken back to the 'Add/Edit Scope' page where the first line will now display the selected scope. Clicking the 'X' will remove the scope and you can then click on the magnifying glass again to return to the scope selection window.

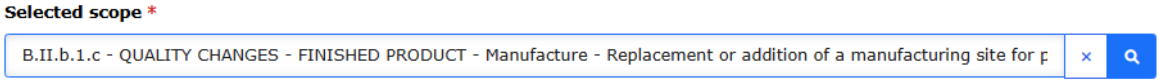


Figure 51 - Cancel and Select Scope

7. Click on the magnifying glass to 'Select Procedure Type'

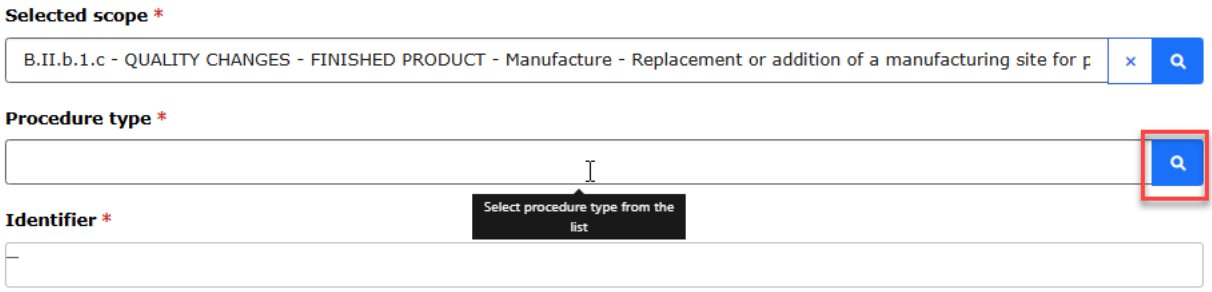


Figure 52 - Select Procedure Type

A list of available Procedure Types will be displayed. You can only select one procedure type from the list. The list can be filtered using the search bar on the top right-hand corner.

8. Click anywhere on the line to select the procedure type and then click the Select button to confirm the selection of the procedure type. If the procedure type you wish to select is not available, however, it appears in the classification guideline or should be available based on the business rules, please raise a ticket via the EMA service desk (select eAF request) to request an addition of the procedure type in RMS. Please detail the scope and the procedure type you wish to add and add justification why this is needed. The new term request process will go through the same process as previously and the new term will appear in the form as soon as it has been added in RMS. The list used in this section is the same as the one used in the interactive pdf variation eAF and as previously, it is known that some scopes or scope/procedure types are missing from the list. This is a known data quality issue that continuously try to improve based on change requests received from users.

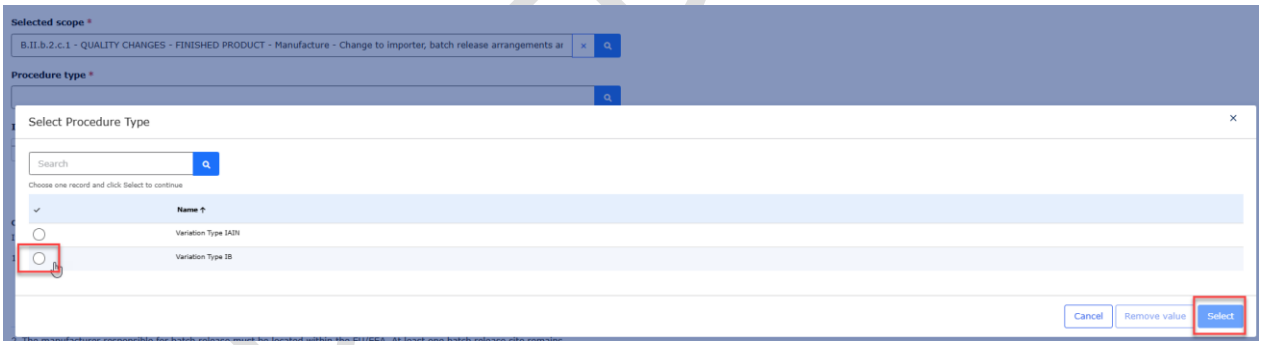


Figure 53 - Select Procedure Type

9. Depending on the selected Procedure type, further options will become available for selection:

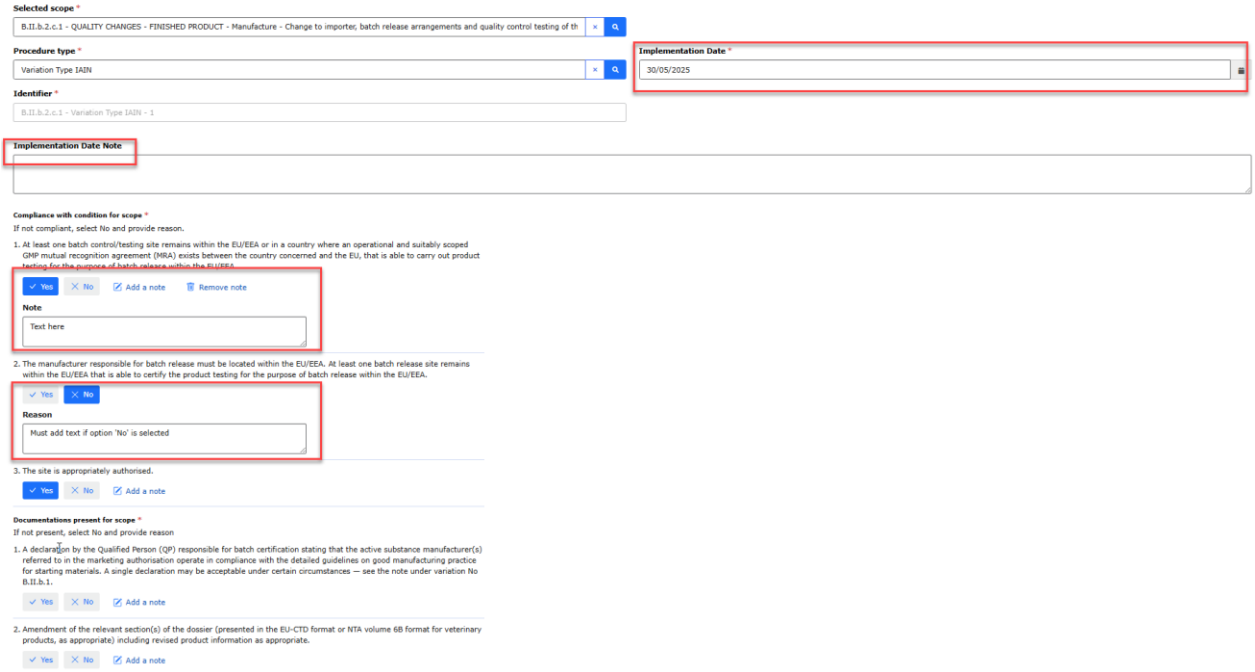


Figure 54 - Option Selection

For Type IA/Type IA_{IN} you must add an Implementation date (either by selecting it from a calendar or by providing the date in format DD/MM/YYYY e.g.: 31/05/2025). Alternatively, or in addition, you can also provide an Implementation Date Note (free text field). For Type IA/Type IA_{IN} it is mandatory to provide a date or note.

Depending on the selected procedure type, related Conditions and Documentations will be listed. Please select Yes' or No option as appropriate. Please note that selection of conditions and documentations or adding a note is mandatory. If you do not meet the conditions or cannot provide the documentation, please add a note (Reason) using the Add a note button. This will launch a free text field for note/justification.

Note that removing the scope or procedure type (using the x button) can remove all selections from the section below (i.e. if you have selected Type IA and added implementation note and subsequently selected conditions and documentations and added notes and you proceed to delete the procedure type and change it to Type IB, the previously made selections may be lost as they are scope and procedure type specific. In some cases they are the same so information is kept, however, it is strongly advised to review the selections carefully if the procedure type is changed and previously selected selections remain ticked.

10. Click the Save button to save your selection. If you do not wish to save your selection, you can press the Cancel button.

Upon clicking the Save button you will be taken back to main 'Type(s) of Change(s)' page where you can see the summary of the selected

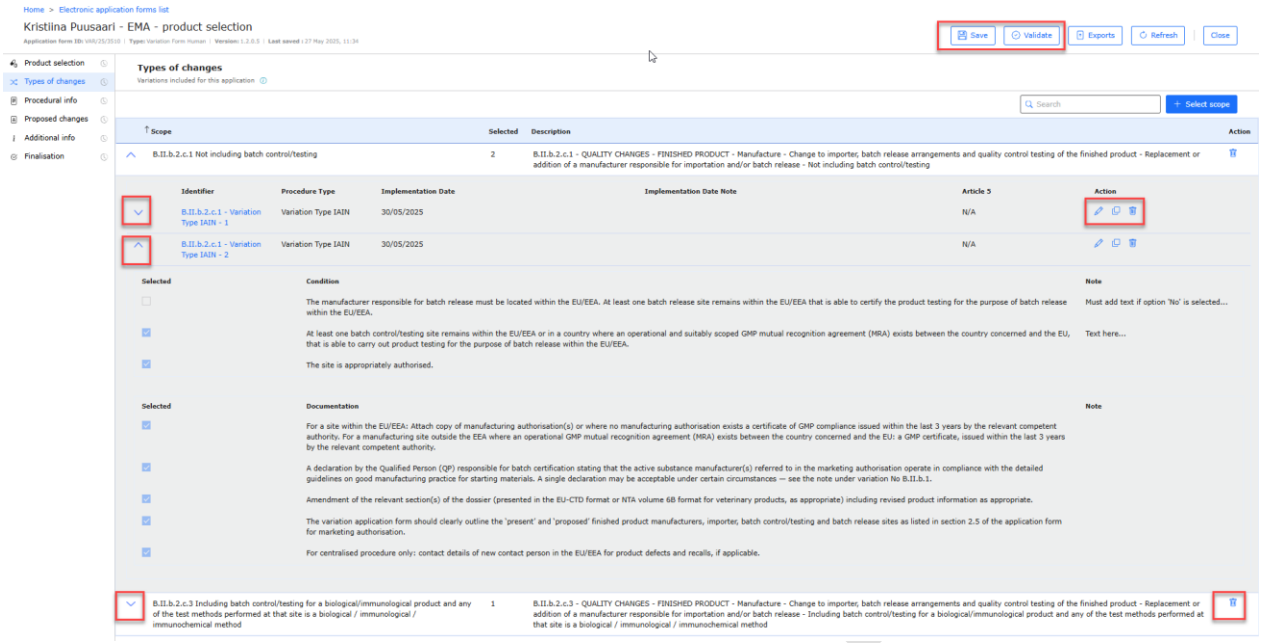


Figure 55 - Summary of Selection

Here you can expand the selection to display the procedure type in conjunction with the scope and to view the Implementation date/note. It is also possible to select to delete the scope or Edit/Delete the procedure type.

11. If you need to add the same scope more than one, please use the '**Clone scope**' button. This will allow fast and easy way to include the same scope in the form multiple times. If you do not wish to use the clone feature, it is also possible to add the same scope multiple times or to select a different scope, please repeat the step by clicking 'Add scope' button. You can do this as many times as needed.

12. Please note that if the same scope is added multiple times, either manually or using clone scope function, these are differentiated by using a sequential number for each scope. This will help you to identify the scopes when you are linking the scopes and the packaged medicinal products in Present and Proposed section.

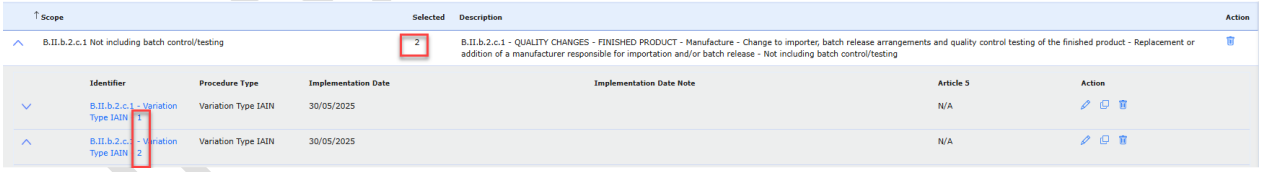


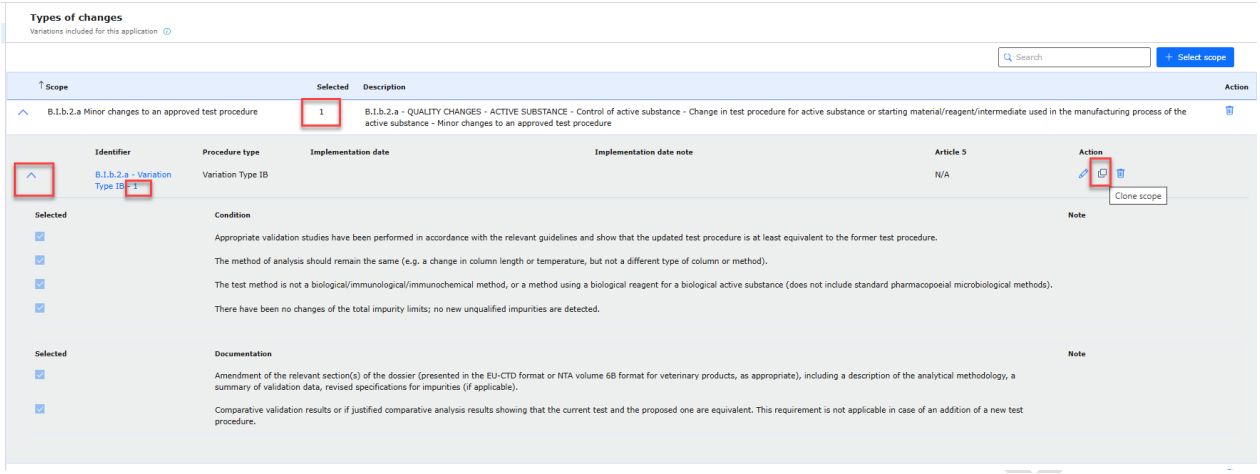
Figure 56 - Add Scope

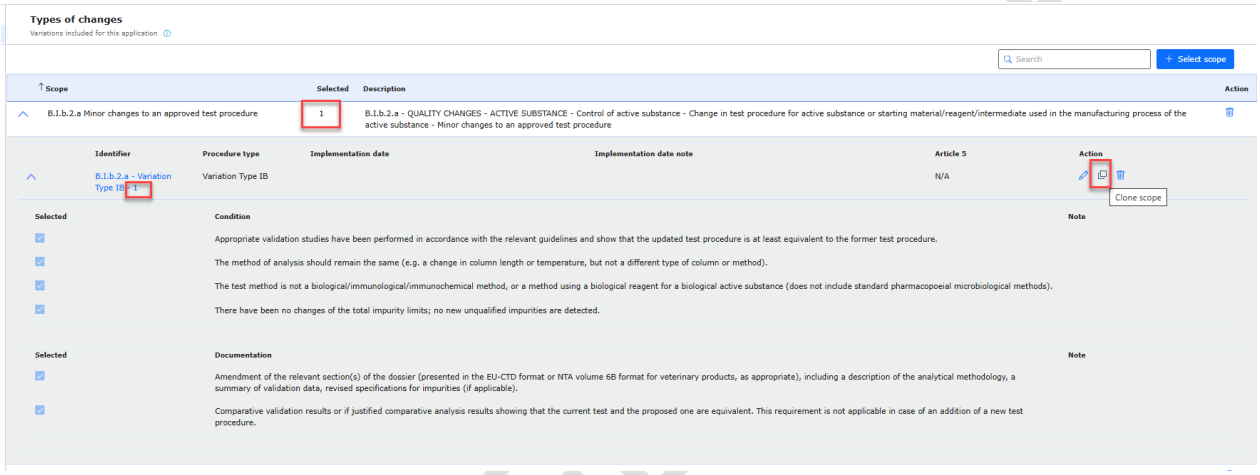
13. Click on the Save button to ensure that you save the changes you made i.e. to save the selected scope(s). You may want to click on the Validate button to change the status of this section to Completed.

2.3.2. Clone scope

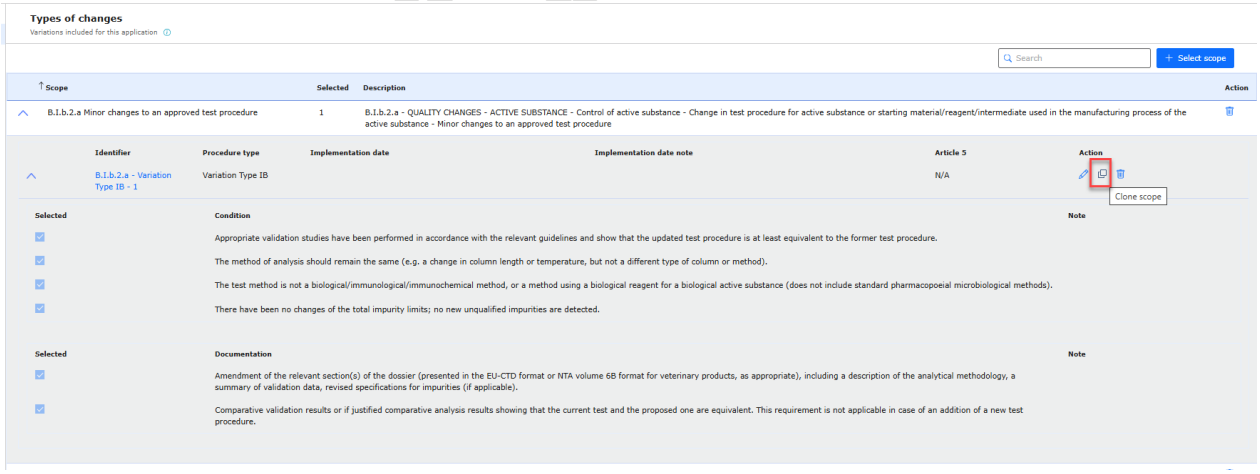
- In order to clone the scope, you will need to have added at least one scope in the form. View the added scope(s) and expand the details of the scope to 'clone scope'

- Click on the arrow on the left of "Scope" to have a full overview of the scope.

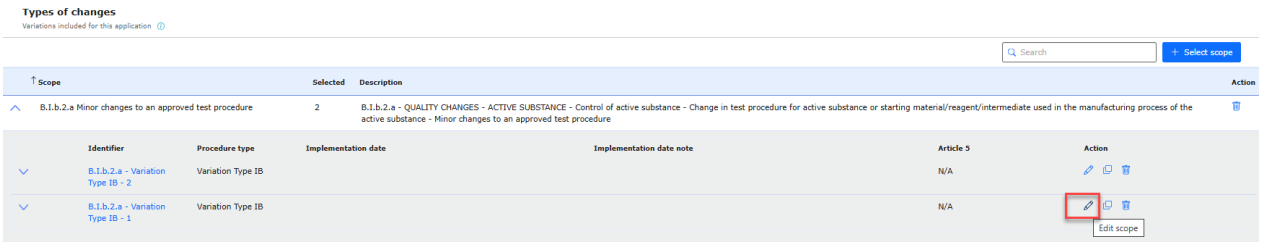




- Click on the clone scope imageat the far right of the same row to select “Clone scope” option.



You can repeat the clone scope step as many times as needed. If you need to edit any details of the scopes that you have cloned, simply select the ‘Edit scope’ option and the details are opened for editing, here you can for example add a note or make any other necessary changes



- After the scope is cloned, you will have a second, third etc selected scope, which is attributed a different ID at the end (in the example below, the first scope is n. 1, the cloned one is n.2). Please note that you can clone scope multiple times.

2.3.3. How to delete a scope in an application

Deleting a scope from an Application Form implies to have added at least one variation scope to that same form previously. See section 2.3.1 on how to add a scope.

1. Access an existing or create a new Application Form. See sections, 2.1.2and 2.1.3 for further details
2. In the Type(s) of Change(s) page, click the trashcan (bin) image at the end of the row of the scope you wish to delete.

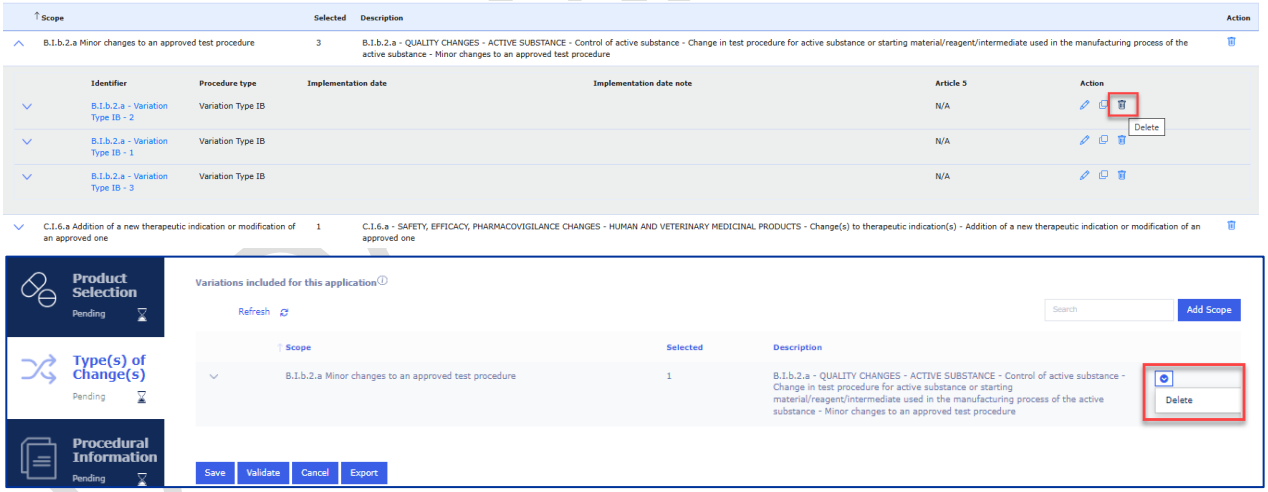


Figure 57 - Delete Scope

If you only wish to change the procedure type, for example from Type IA to Type IB, please expand the selection using the down arrow and click to 'Edit' option indicated by a image of a pen. Once you have clicked 'Edit scope' you are back in the screen where you can select the procedure type and any conditions/documentations where relevant. Please click save to save the selection.

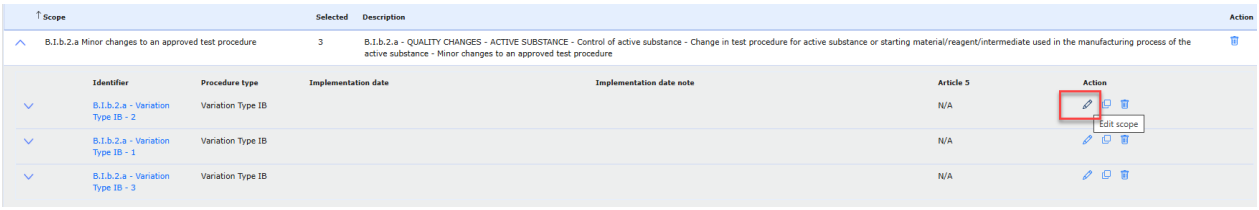


Figure 58 - Edit Scope

2.3.4. How to delete a scope in an application

Deleting a scope from an Application Form implies to have added at least one variation scope to that same form previously. See section 2.3.1 on how to add a scope.

1. Access an existing or create a new Application Form. See sections 2.1.2and 2.1.3 for further details
2. In the Type(s) of Change(s) page, click the small arrow at the end of the scope you wish to delete and select 'Delete'.

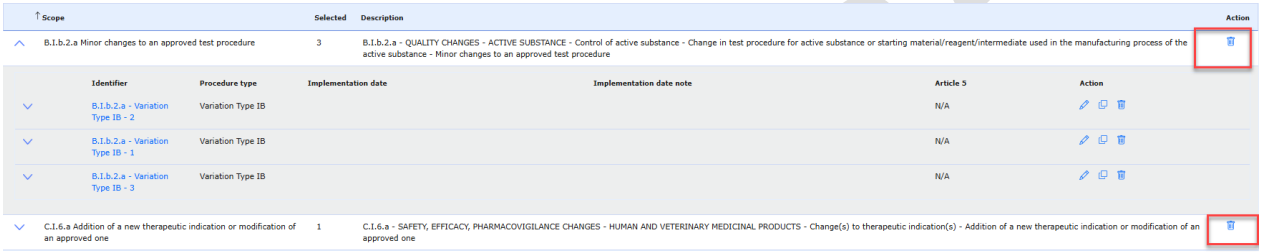


Figure 59 - Delete Scope

If you have selected more than one scope and procedure type, you can delete single scope/procedure type combination in the sub-selection window by clicking 'Delete'. If you have only one scope selected, the 'Delete' button will remove the whole scope.

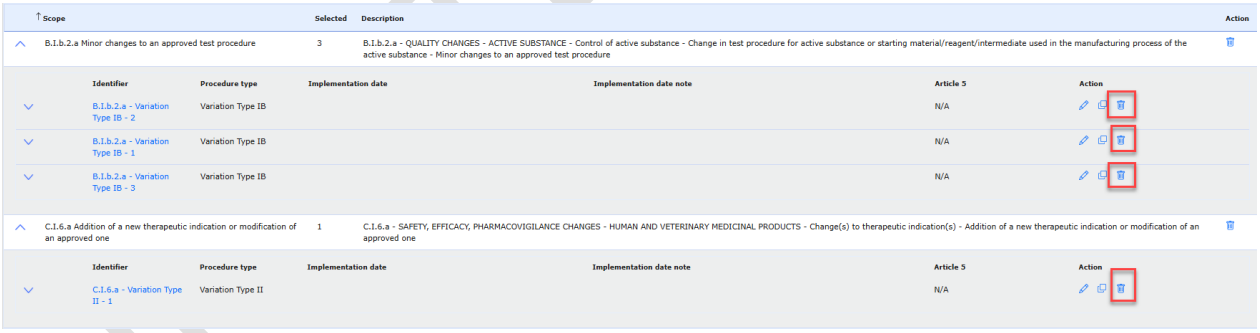


Figure 60 - Edit Scope

2.4. Procedural Information

The procedural information section fills in the 'section 1' of the pdf eAF. This section has been divided in 3 sub sections of which 2 are always displayed..

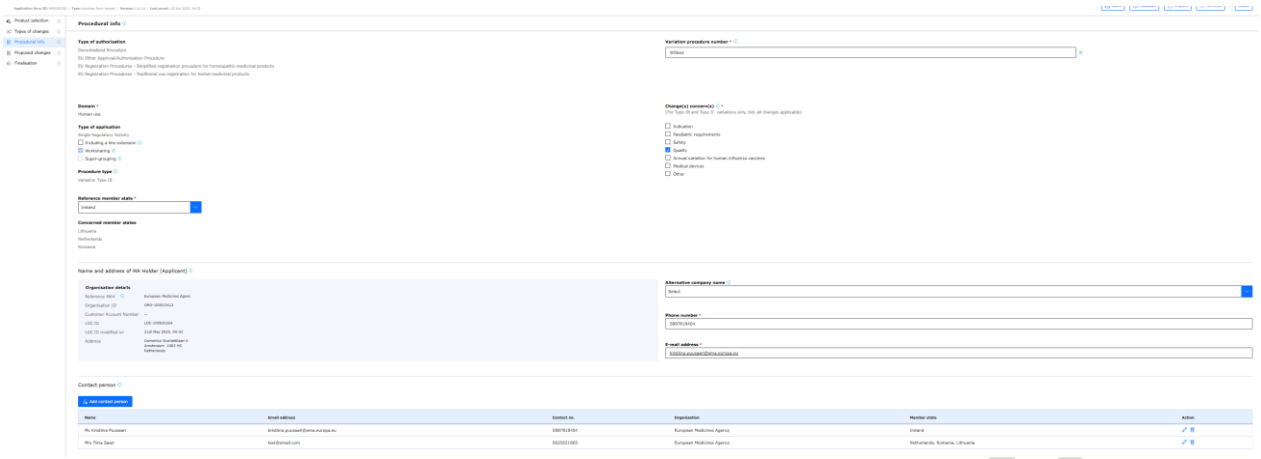


Figure 61 - Procedural Information Section Overview

2.4.1. Procedural Information

In this section, the information is mainly **pre-filled and calculated** based on selections done in Production Selection and Type(s) of Change(s) sections.

It is not possible to manually edit these selections for product and procedure types.

NOTE: Please note that there is a delay in the automated calculations on this page – this is a feature of the tool used, not a bug. It can take *several* minutes before the correct calculations are displayed. It may help to refresh the browser to display the correct calculations slightly faster.

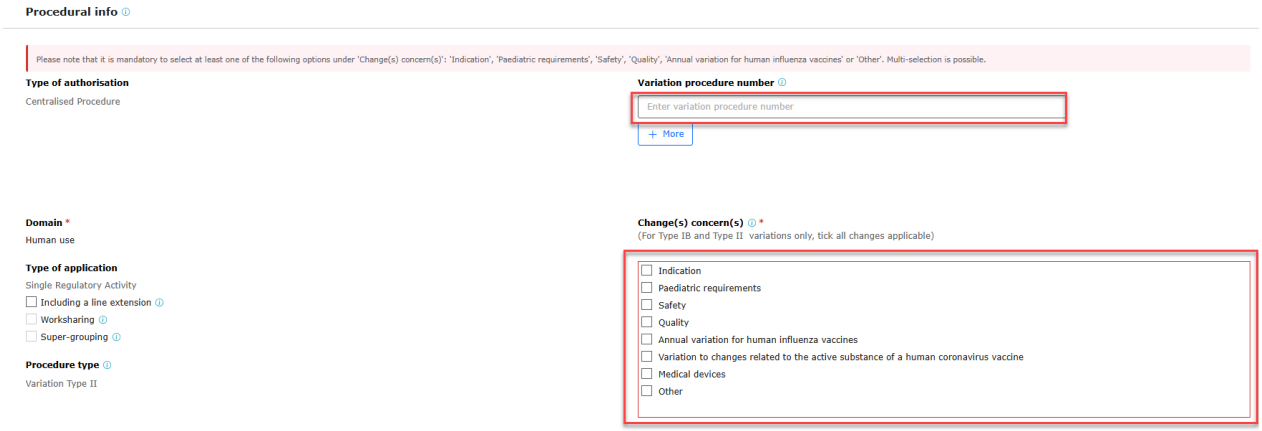


Figure 62 - Sub-section: Procedural Information

- *Domain: This is always 'Human Use' as the variation form currently only contains human medicinal products.*
- *Worksharing; this field is auto calculated and is ticked by the system when more than one 'Centrally Authorised Products' (CAPs) i.e. products with different EMEA/H/ number have been selected or when a mix of different CAPs and non-CAPs or a mix of different non-CAPs are selected. Please note that the product selection is on 'Medicinal Product' level i.e. if the product selected has for example more than 1 pharmaceutical forms, and your change impacts all 'medicinal products' you should select them all, but this does not mean that the work-sharing tick box will be ticked.*

Supergrouping; this field is auto calculated and is ticked by the system when more than one CAPs (only) or non-CAPs only (as per the current variation regulation rules) has been selected and in addition to one or more Type IA and/or Type IA$_{IN}$ scopes have been selected.

- *Procedure Type; this field will display the name(s) procedure type(s) selected in the Type(s) of Change(s) section (For example Variation Type II).*
- *Type of Authorisation; This field is auto filled based on the type of authorisation procedure of the selected product(s).*

These are the only sections in Procedural information that can be edited manually;

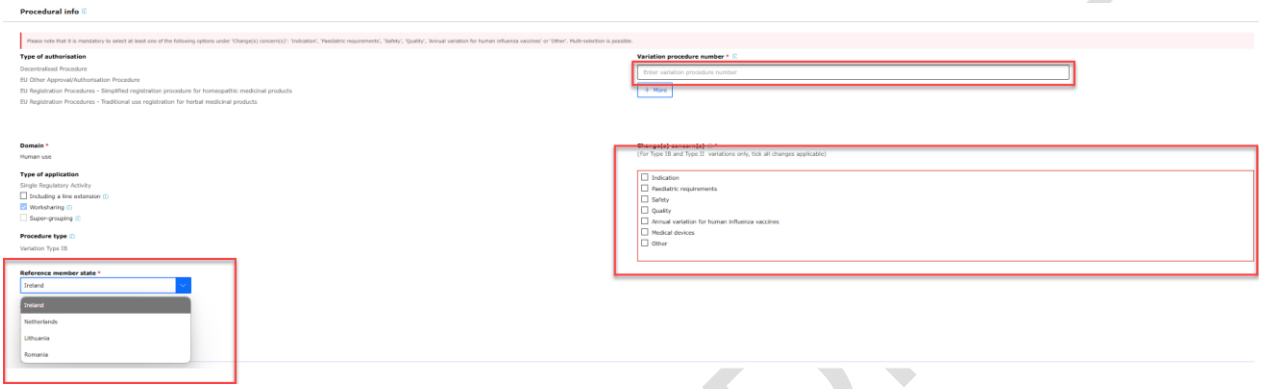


Figure 63 - Example of non-CAP Type IB variation procedural information section

- *Medical Device; this tick box is available for all procedure types and should be selected if the section 4d of the pdf needs to be filled i.e. for classifications (scopes) related to Medical Devices e.g. B.IV.1.a.1. Please note that **ticking this box will not automatically display the fields for Medical Devices in Proposed changes section**, please see the section 2.5.3.5 Medical Devices on **how to enter the data** in the medical devices section.*
- *Change(s) concern(s); this sub selection is **only** visible if **Type IB or Type II** has been selected in Type(s) of Change(s) section. Please note that option 'Variation to changes related to the active substance of a human coronavirus vaccine' will only appear when Type II is selected and, please note, this option can only be selected in addition of another option in Change(s) concern(s) e.g. safety, this implementation is aligned with the business rules in the interactive pdf eAF.*
- *Variation Procedure Number; An editable free text field to include the variation procedure number for validation-response, or for example the WS or IG number. For CAPs this is an optional field. For mixed CAP and non-CAP WS variations, this is a mandatory field. For example for MRP variations, the MRP variation number should be added here. More information on the use of the variation procedure number can be found from the guidance here.*

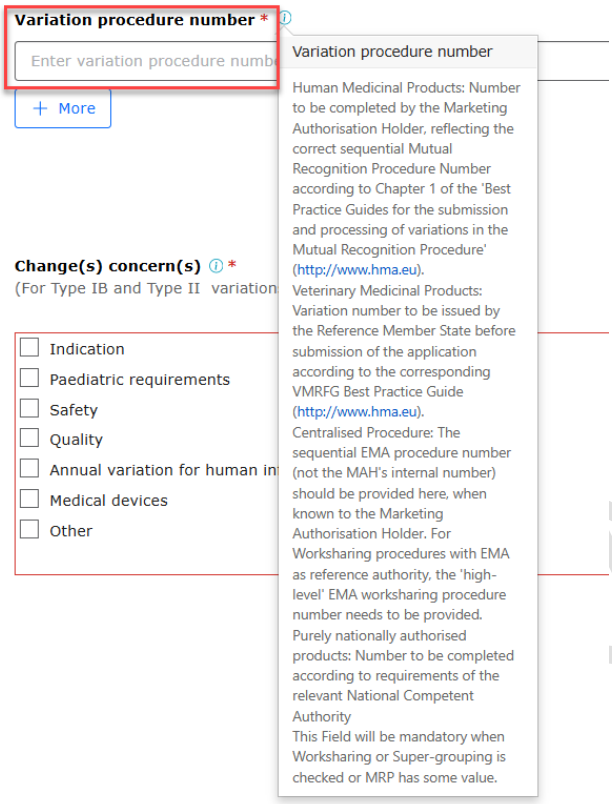


Figure 64 - Variation Procedure Number

- *For WS and Supergrouping variations containing products authorised in different countries (excluding CAPs), the user must select the Reference Member State from drop down menu of available countries. The other countries will be automatically listed as CMS. Please note that it can take some moments before the list of CMS is displayed, you may need to click 'save' and 'validate' to see the list of CMS.*

  *For WS variations containing CAPs and non-CAPs the RMS is always 'European Union'. In these cases the RMS and CMS fields are auto-filled by the system and the RMS **cannot** be manually edited.*

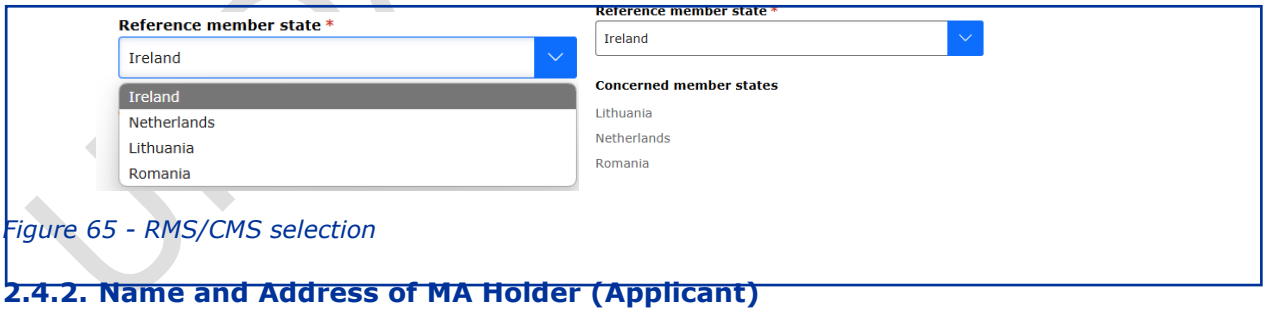


Figure 65 - RMS/CMS selection

2.4.2. Name and Address of MA Holder (Applicant)

The MAH Name and Address are **auto filled** based on the selection of the MAH when the form is initially created (see section 2.1.2 How to create a new Application Form) and it is **non-editable**. If you do need to change the MAH for your application, you will need to create a new application form, it is not possible to edit the MAH selection once the 'Create & Next' has been pressed.

It is now possible to select an '**Alternative company name**' if available in OMS. This is completely optional feature and should only be used if needed. The alternative organisation/company name may be particularly useful in cases where there are certificates/registration documents where the company name

is not the same as the preferred MAH name in OMS. Only a single alternative name can be selected, and it will be displayed in the pdf form under the MAH name. The OMS-id and LOC-id are identical for the 'OMS preferred name' and for the 'Alternative company name'. Not all organisations have alternative names available in OMS.

The alternative company name is currently only available in the MAH details section.

Please add the telephone number and the email address for the MAH in the free text fields.

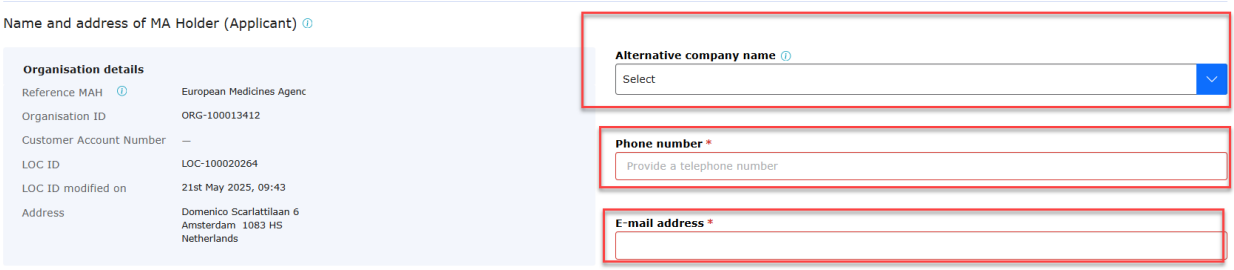


Figure 66 - Name and Address of MA Holder (Applicant)

2.4.3. Contact Person

The contact person field is not autofilled and it is **not** possible to select from previously selected addresses (this is to avoid accidental selection of the MAH organisation where the MAH contact person has different address).

Note for procedures managed in IRIS: For centrally approved products, the default contact person is the product contact declared to EMA (the person authorised for communication between MAH and authorities after authorisation, as specified in section 2.4.3 in Part IA/Module 1 Application Form for the marketing authorisation application). Following submission, the contact person recorded with EMA can change the case contact directly in IRIS.

1. Click the + Add button

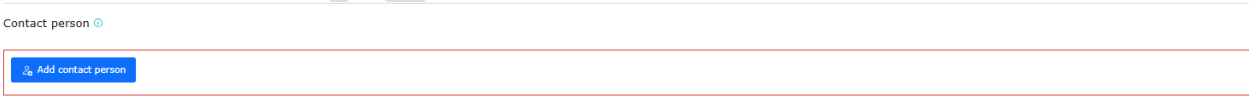


Figure 67 - Contact Person

2. In the Create Application Contact subpage, enter the Contact person name, email address, phone number and title (e.g. Mr/Ms) in the free text fields.

Please note that for CAP and EMA led CAP/non-CAP WS applications, the Member State for the contact is always European Union and the field is **auto filled and cannot be changed**. There can only be **one contact person for CP applications**. It is **not** possible to add contact persons for the other member states in mixed WS applications.

For non-CAP applications, please use the multiselect member states function where needed (i.e. there is a single contact person for products from multiple different member states) or select each member state separately and provide the Contact person contact details for each member state representative where relevant. Please note that the 'Member state' should reflect the member state where the product is authorised, not the member state/country where the contact person is located. The contact person can

be located in a different country and one contact person can be a contact person for multiple different products authorised in different member states.

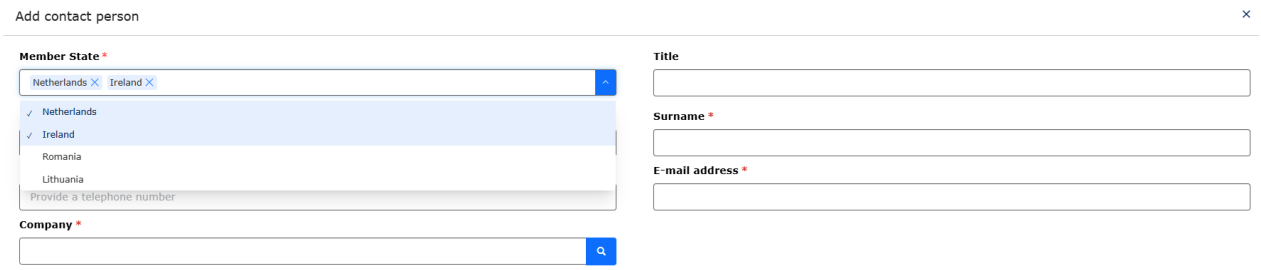


Figure 68 - Create Application Contact

3. Click on the magnifying glass to launch the OMS search to add the contact person organisation. You can search by the Organisation Name, address (also partial address e.g. Finland), ORG or LOC-id

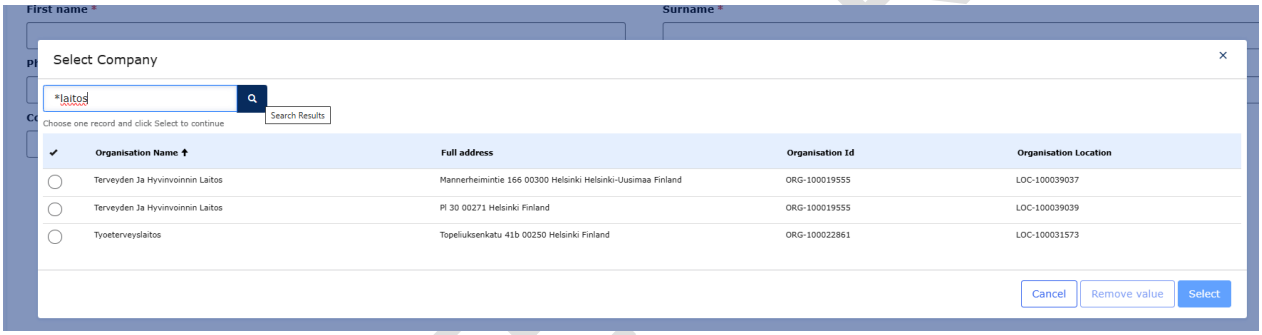


Figure 69 - Lookup Records

4. Click on the Select button and you will be taken back to the Create Application Contact page where you can view the selected organisation details and finalise adding the contact details

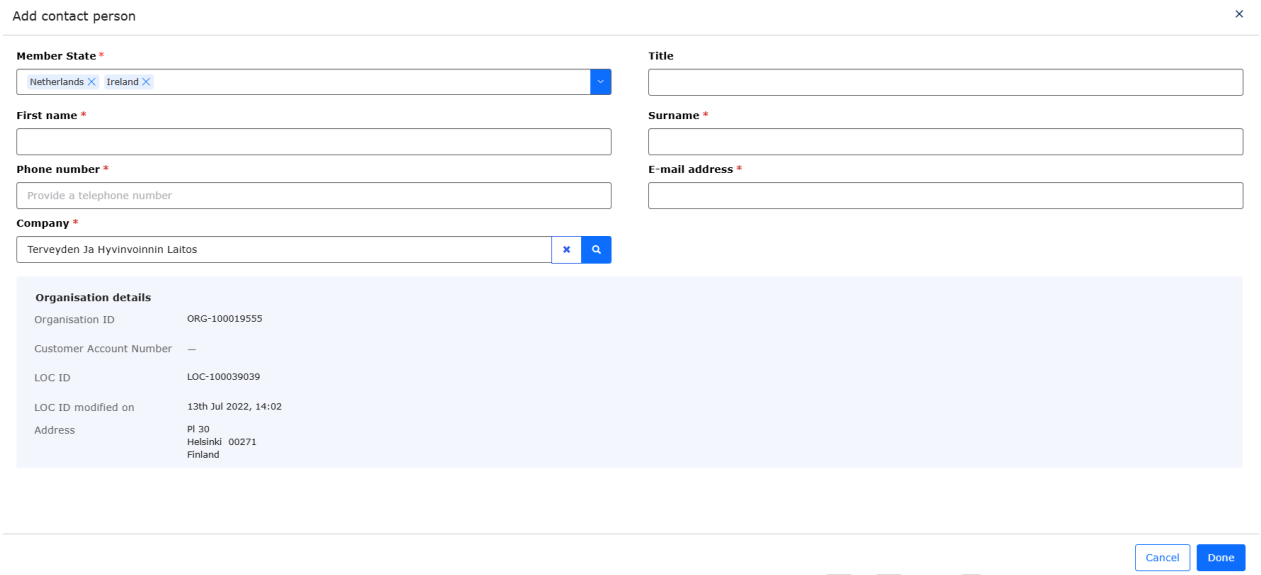


Figure 70 - Contact Person Details

5. Click on the Save button and you will be taken back to the Procedural Information main page
6. Click on the Save button to save your changes. You may want to click on the Validate button to change the status of this section to Completed

2.5. Proposed Changes

The proposed changes section contains most of the fields that are present in section 3 of pdf eAF. Refer to the Proposed Changes Selection step on the left-hand side of the menu.

NOTE: Please note that the eAF team is implementing an updated user interface design across the whole web-based eAF. The changes are implemented in small batches where various pages might present either the new or the old design. In some pages, the implementation is partial, and features and functionalities will be completed in various sprints.

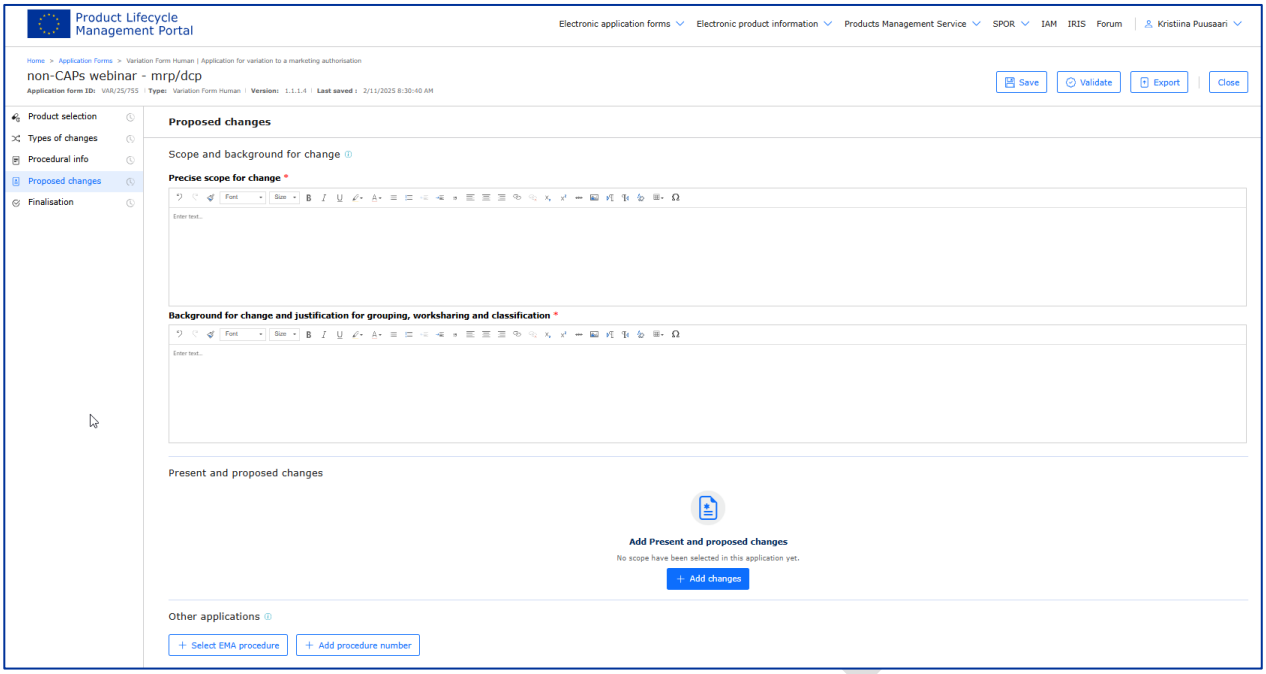


Figure 71 - Proposed Changes

2.5.1. Precise Scope and Background for Change

The actual changes that are being applied for should be stated in a concise way and a brief explanation provided of why the change is required.

Please ensure that you press Save after filling in the Precise Scope and Background for Change before navigating away from this section to prevent **losing** any changes.

1. Access an existing or create a new Application Form. See sections 2.1.2and 2.1.3 for further details
2. Enter the Precise Scope for Change and Background for change in the corresponding free text fields. You can paste text into this field from another document (plain text only will be copied, you will need to manually edit the text if you wish to add for example underlined or **bold** text. You can also add images and tables.

A link to EMA's published Guidance for the applicants for the preparation of the precise scope section of the variation application form is available from the Information button in Precise Scope section. This document opens in a separate tab.

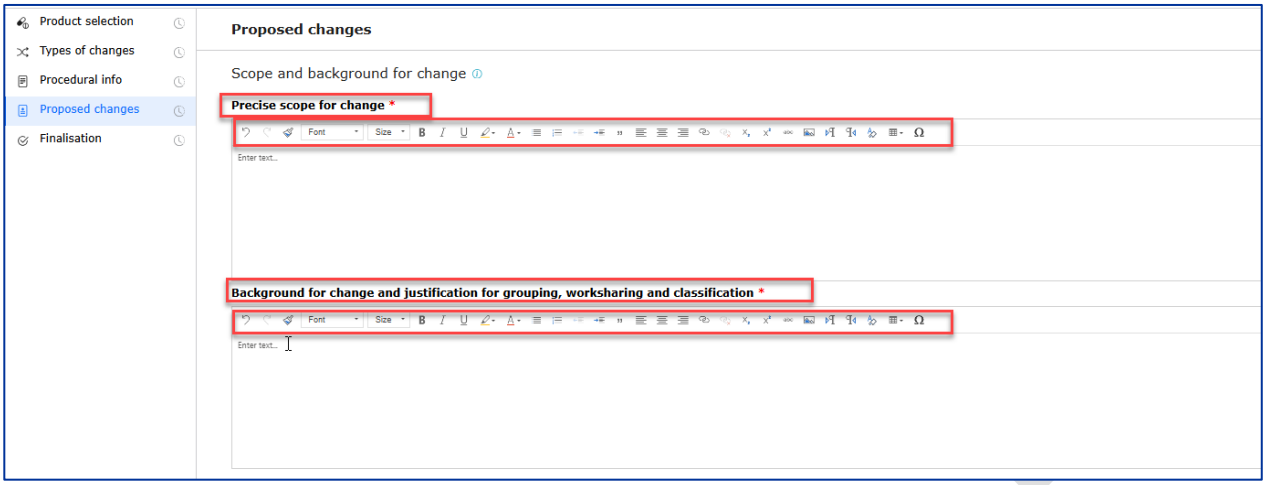


Figure 72 - Precise Scope and Background for Change

2.5.2. Present and Proposed Changes

NOTE: The eAF team is aware of the limitations and challenges related to the current implementation of the Present and Proposed section and hence, we are currently working on implementing further improvements to this section. The changes will be implemented during 2025 and will bring further **improvements and changes to the layout and usability** of this important section in the form. It will become easier to edit information in both present and proposed fields. We are additionally implementing performance improvements and new user interface designs to this area of the form, however, these changes will be implemented incrementally

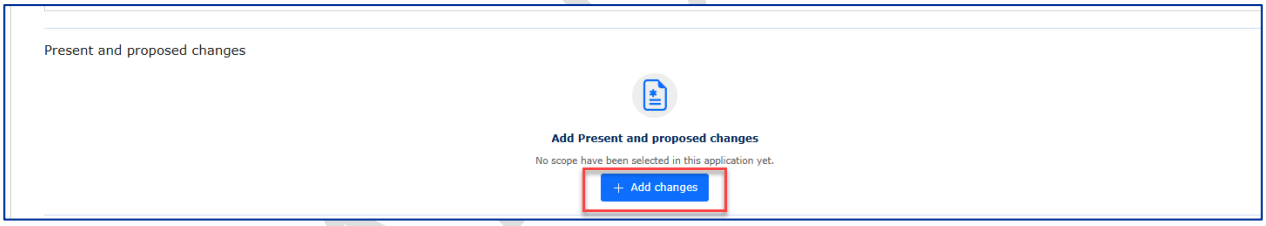


Figure 73 - Proposed Changes

2.5.2.1. How to map a product to a scope change in an Application Form

1. The first step in the updated design for the Present and Proposed section is to click the + Add changes button to launch the section.
2. In the 'Select scope for proposed changes' tab you can see all the scopes you selected earlier in section Type(s) of Change(s). Select the one(s) that you would like to link to a specific product/presentation.

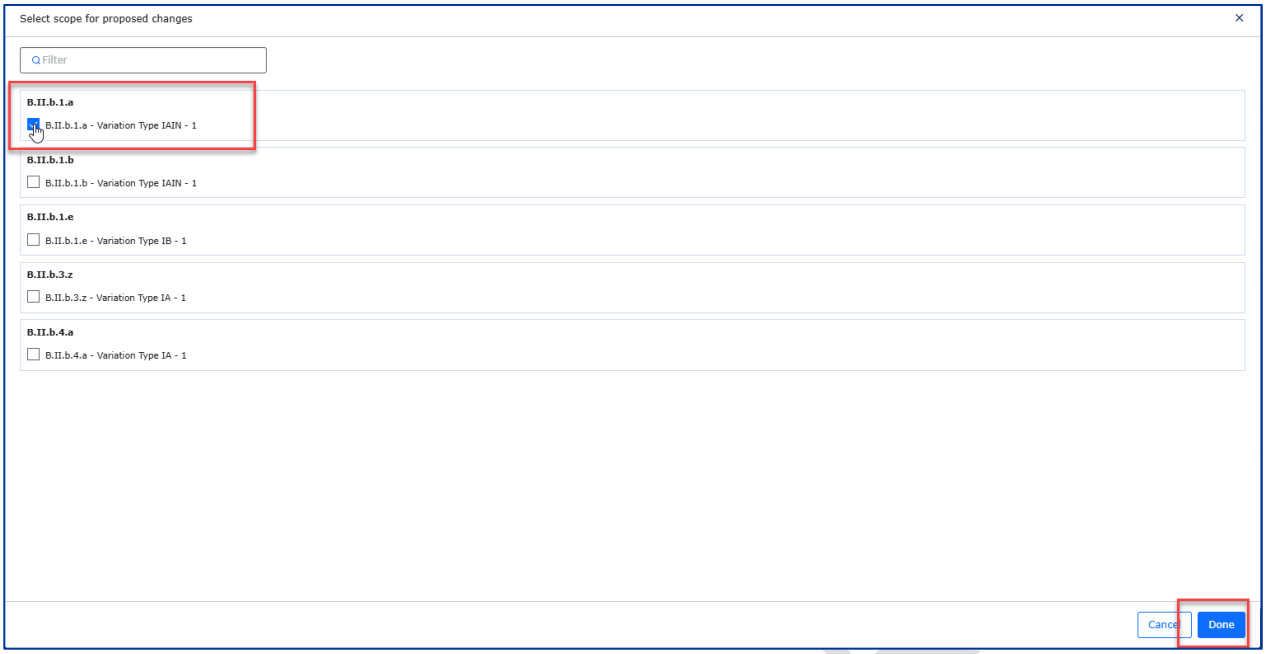


Figure 74 - Selection of Scope and Medicinal Product

3. For **non-CAPs only** (i.e. products authorised through non-centralised procedure i.e. **NP, MRP or DCP**): all products and presentations are **automatically selected**, and it is **not** possible to unselect them.

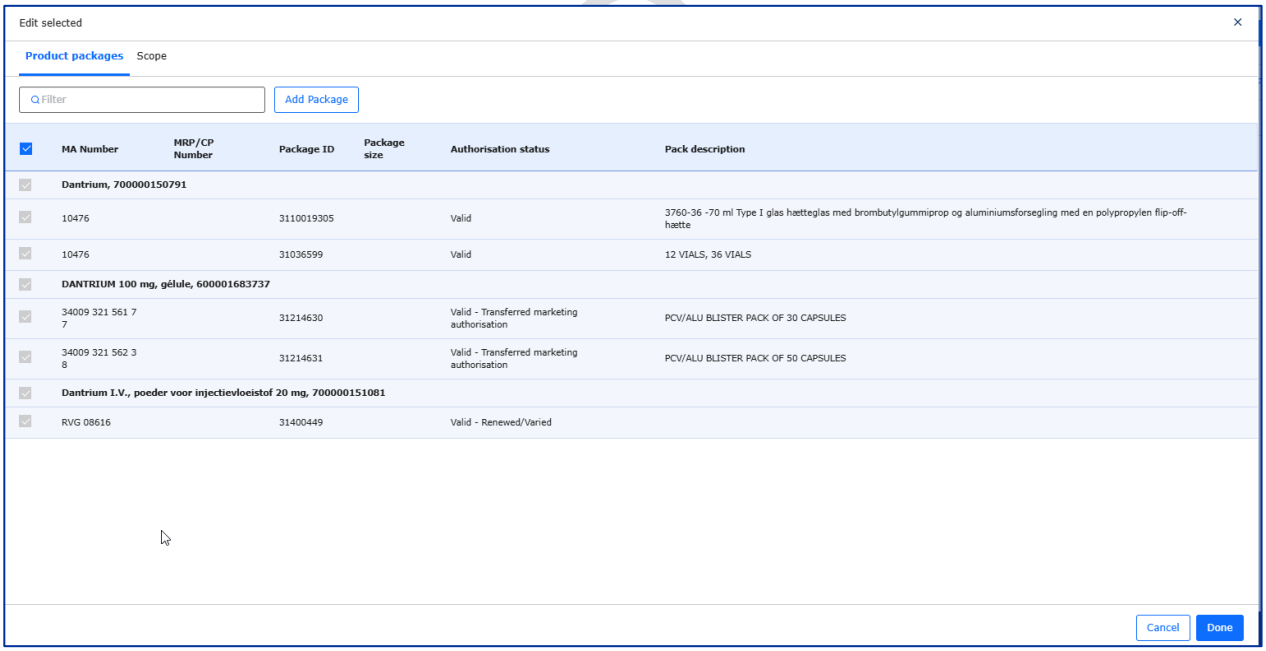


Figure 75 - Selection of Scope and Identifier (non-CAP)

4. For **CAPs only:** the packages can be selected separately e.g. if the variation only impacts certain packages/pack-sizes, it is possible to select only those packages/pack-sizes relevant to each scope. This is an important step as the **selections of the Packaged Medicinal Products in this section defines which MA numbers are listed in section 2 of pdf** output form.

    a. All packages are initially auto-selected, however it is possible to edit the selection for CAPs by clicking the 'Edit and add package button'.

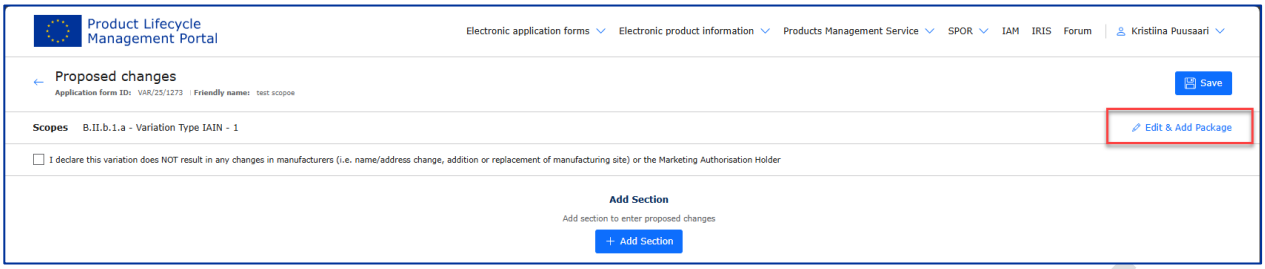


Figure 76 - Linking CAP Packages to Scopes

b. This function launches another submenu where all products and packages (pack-sizes) are listed. You can de-select those presentations that are **not impacted by the selected scope**

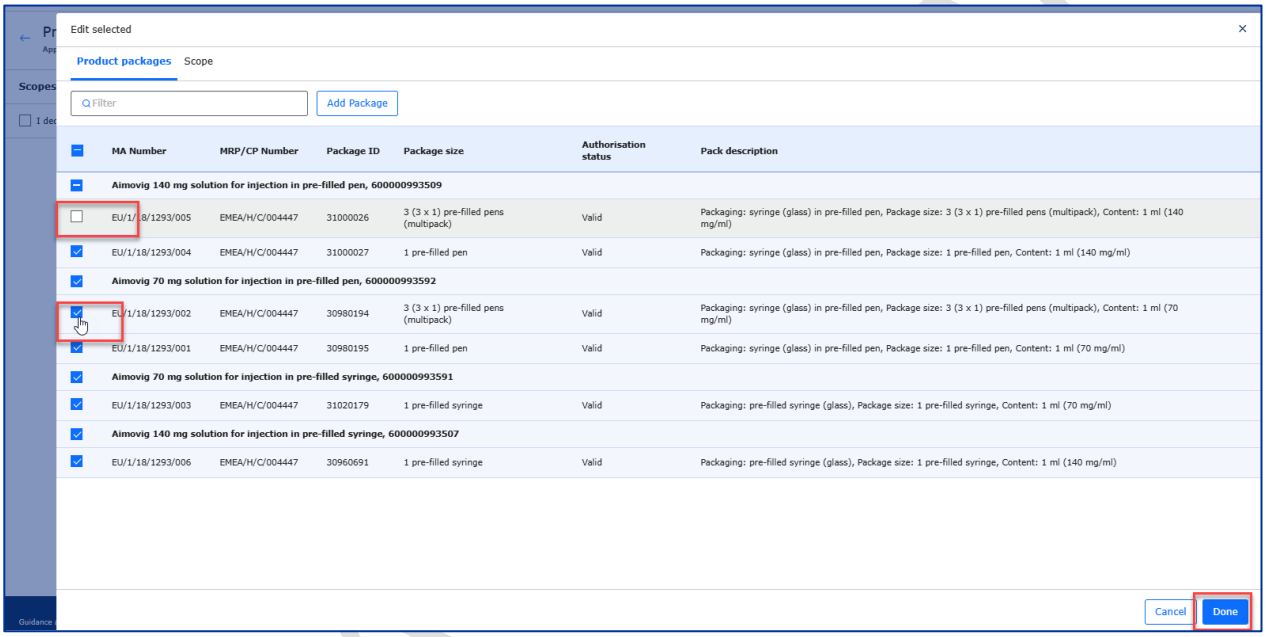


Figure 77 - Deselecting packaged medicinal products

c. If all changes concern all products/presentations, simply leave all packaged medicinal products selected. You can repeat this step to link the changes in present and proposed to a particular scope/product combination as many times as necessary.

d. You **must** select **at least one scope** and **one packaged medicinal product for each combination**. All listed scopes must be selected in the form and linked to at least one packaged medicinal product (i.e. to at least one MA number).

5. Select the related Medicinal Product(s)/presentations and click Done to return to the Present and Proposed to add details of the changes or to continue filling other sections. If you have multiple changes/scopes that impact only part of the selected products, repeat this change to indicate the changes linked to those scopes.

6. Previously added sections in the present and proposed section are listed in the main view. If you have multiple changes/scopes that impact only part of the products selected, repeat this change to indicate the changes linked to those scopes. To repeat the step click on Add Changes. The selected scopes and products will be shown and can be edited.

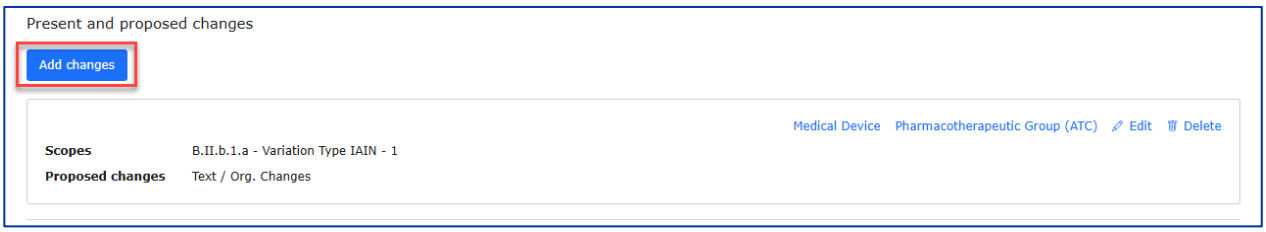


Figure 78 - Add Changes

2.5.2.2. Present and Proposed Text Changes

7. Once you have combined the scope(s) and packaged medicinal product(s) (i.e. presentation(s) you wish to link to together, please click + Add section to continue to fill in the free text fields to provide the changes in the Present and Proposed fields.

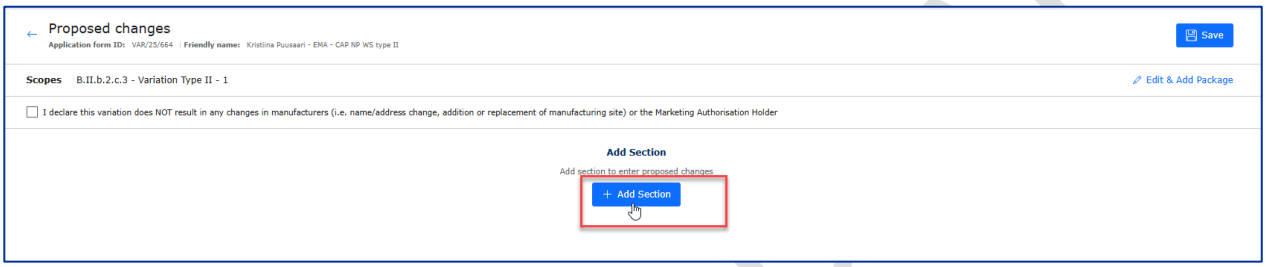


Figure 79 - Present and Proposed Scope Selection

8. When you click 'Add section' a pop up will be launched, this function allows you to create multiple different free text fields, in comparison to the interactive pdf form, the + button in the present and proposed section would give you the same option. You can give each section a name if you wish to help you to edit the form, for example you can name the sections with the sections of the SmPC. This is a completely optional step and the name of the section will not be visible in the pdf.

   If you do not wish to provide a section title, simply click 'Done' to proceed to fill in the Present and Proposed fields.

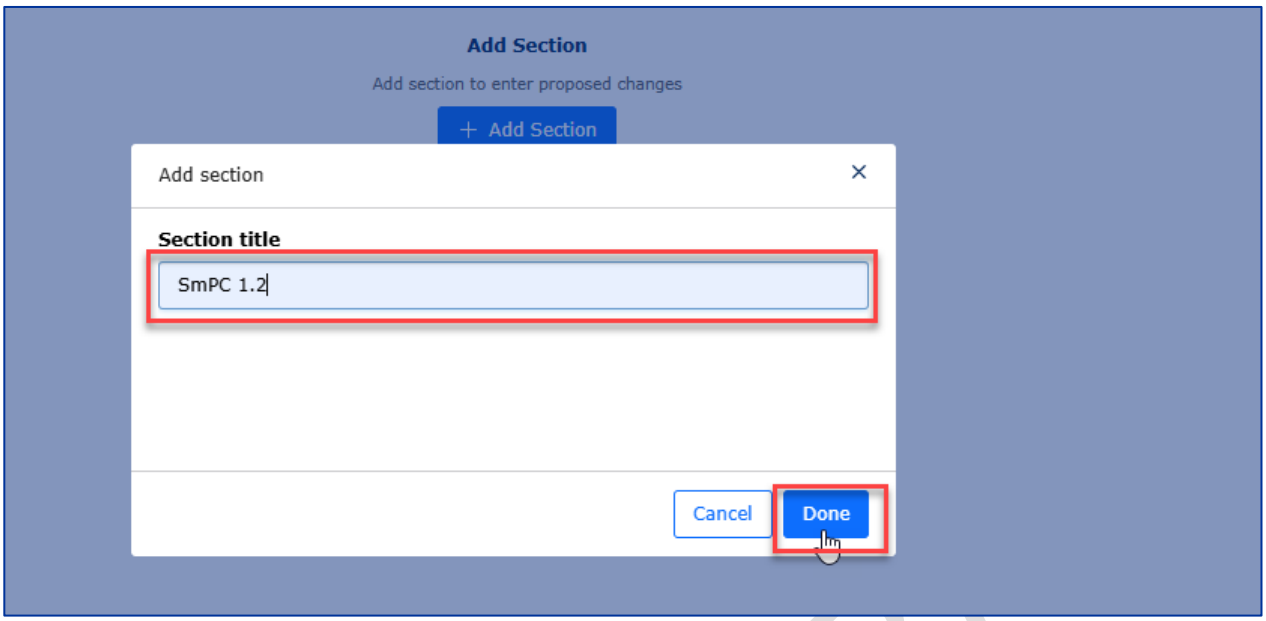


Figure 80 - Section Title Example

9. If you would like to add multiple different free text boxes to the present and proposed section, add as many 'sections' as needed. To repeat the step click on Add Section.

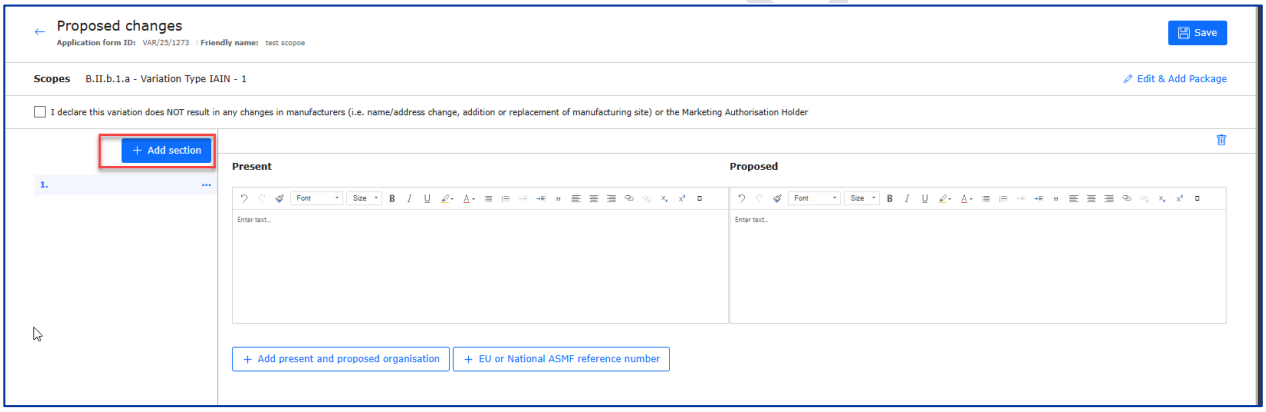


Figure 81 - Adding sections

10. Please add the free text changes and images and make use of the editing options. Please note that depending on your source document you may be only able to paste plain text to these fields from another document. Copying edited text from word (e.g., **bold** or *different* colour text from Present field to Proposed field, the formatting is kept. Multiple images can also be added to these fields. Please note that to keep the fields aligned, if so desired, you can use enter to align information for example on different sections of the relevant text (so that the changes are shown next to each other in the pdf output form. The toolbar can be expanded to show additional editing options by clicking on the small square at the end of the first line of the editing options (shown in red below).

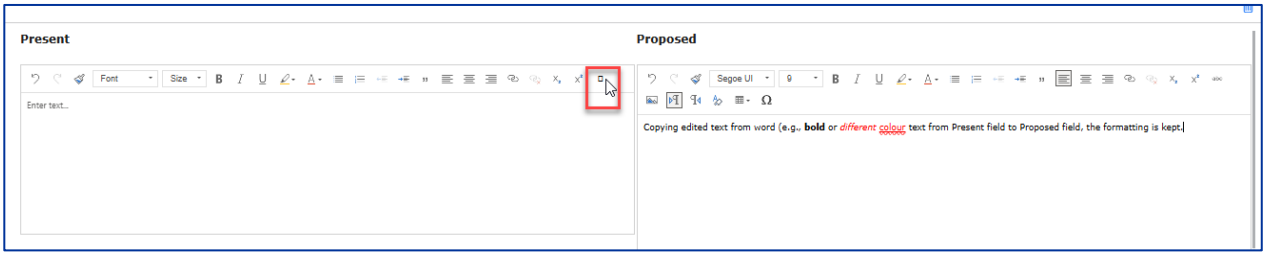


Figure 82 - Editing Present and Proposed Fields

11. You can add as many sections (for each scope) as you wish. Due to a technical limitation, it is not possible to view the multiple sections at the same time, however, you can easily toggle between the different text boxes using the menu on the left where different free text fields have the 'section numbers'. The sections can be named and renamed or even deleted if needed.

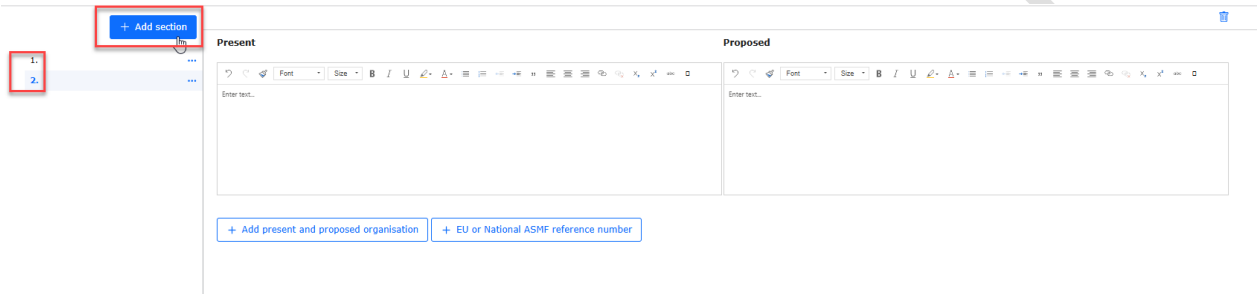


Figure 83 - Add Sections

12. **For CAP only**: Ensure you have either selected Present and Proposed organisations in the Organisation details section or if no organisations are impacted, tick the declaration box to confirm that the variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder. Please see updated European Medicines Agency practical guidance on the application form for centralised type IA and IB variations providing further details on provision of organisational details in the eAF.

13. **Note on deletion of an organisation**: Please note that a **deletion** of an organisation is **not** considered 'a change to the organisation'. In these cases, as it is mandatory to select an organisation in the Proposed field if an organisation is provided in the Present field, please use the free text fields to provide the details of the deletion of an organisation.

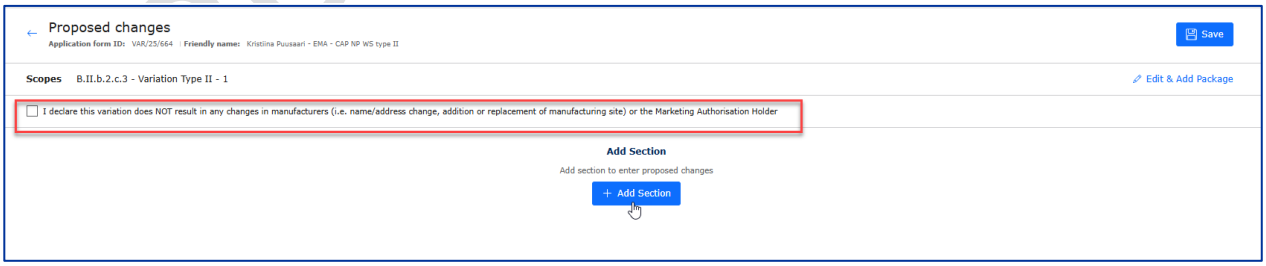


Figure 84 - Mandatory Use of OMS For CAPs

2.5.2.3. Organisation Details

NOTE: The eAF team is aware of number of various issues affecting the OMS integration with the PLM Portal eAF. There are cases where it is not possible to select/find the correct organisation in the eAF although OMS is up to date. In case of an OMS issue, please raise a service desk ticket with detailed

description of the issue and we will review if it is possible to solve the issue. In some cases, the issues are derived from OMS data used in IRIS and it may not be always possible to solve these issues, in these cases, we may have to ask you to revert back to using the interactive pdf eAF to avoid any delays to the application. We are actively trying to solve these issues, however, some require deep analysis and complex technical implementation which will continue in 2025.

NOTE: Alternative organisation names are not yet available in the web based eAF. The eAF team is working on implementing this change which is expected to become available in Q2-Q3 2025.

In order to fill in this section, you must select the products and variation classifications (scopes) in an earlier step.

Please note: In order to ensure you do not to lose any changes, ideally to ensure that you **select organisations that are impacted from OMS as the first step**. Changes added to the Present and Proposed fields may **be lost** if you enter these first and then add an organisation details using the + Add button to select the Present and Proposed organisations.

1. If the change does not concern any organisations, please tick the box to declare that this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder.

NOTE: this tick box will prevent saving the text in the free text fields and combining the scope and presentation. It must be ticked first if no organisation is selected from OMS!

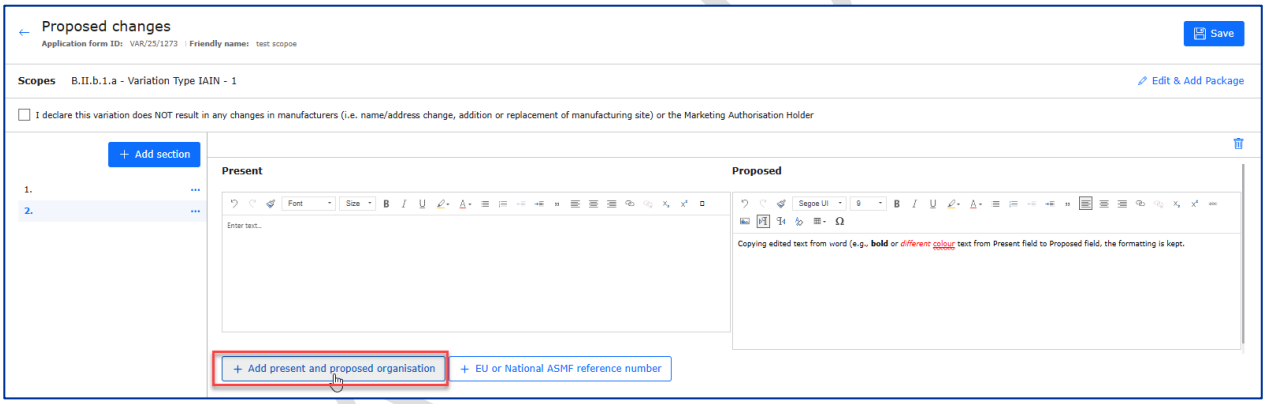


Figure 85 - OMS Changes

2. In the Proposed changes – Present and Proposed Value(s) – Add present and proposed organisation subsection, click on the magnifying glass to launch the OMS search to select the Present and Proposed organisations. The selection of the 'present' organisation(s) is optional.

   If the organisation is not found from OMS, it is possible to manually enter the organisation details on the present organisation.

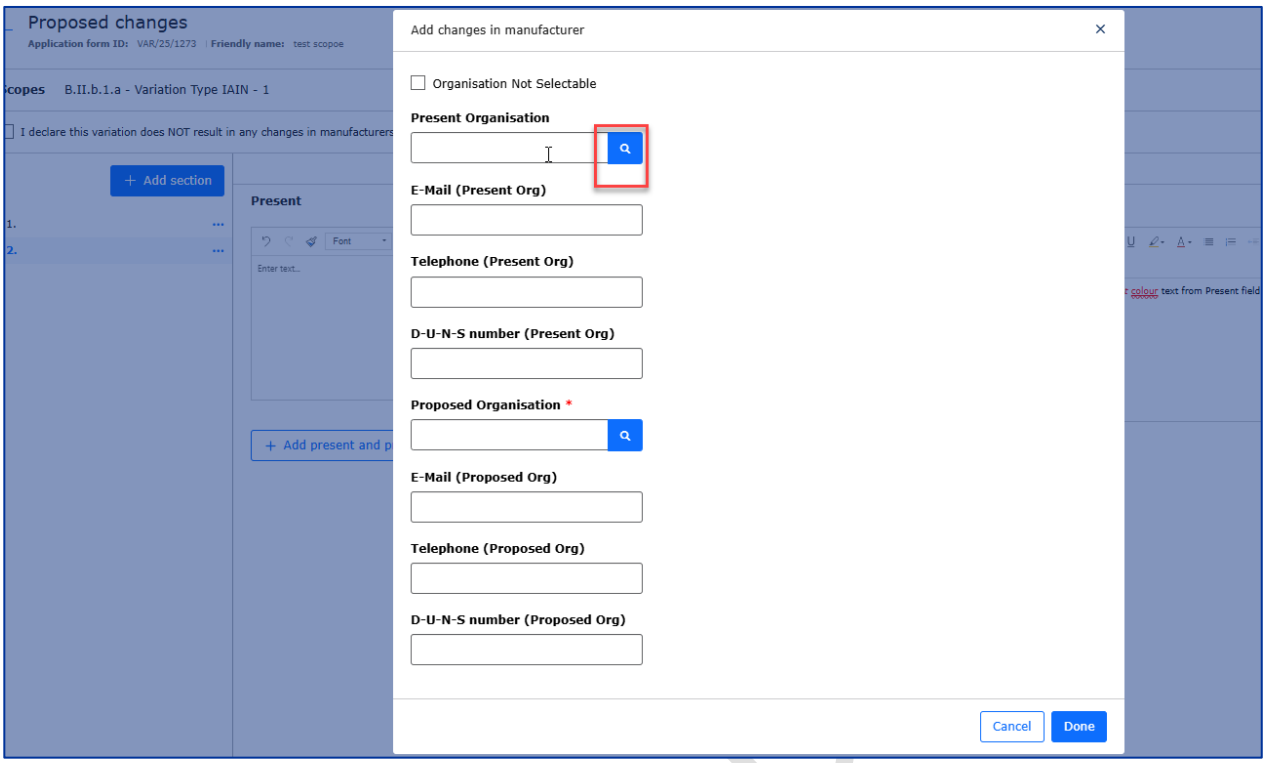


Figure 86 - Proposed Changes - Add/Edit Organisation

3. In the Select Present Organisation, use the search to find the organisation from OMS. You can only select one organisation at the time, however, you can repeat organisation selection as many times as needed. It is possible to toggle between 'active' and 'inactive' organisations (organisation/location status is retrieved from OMS).

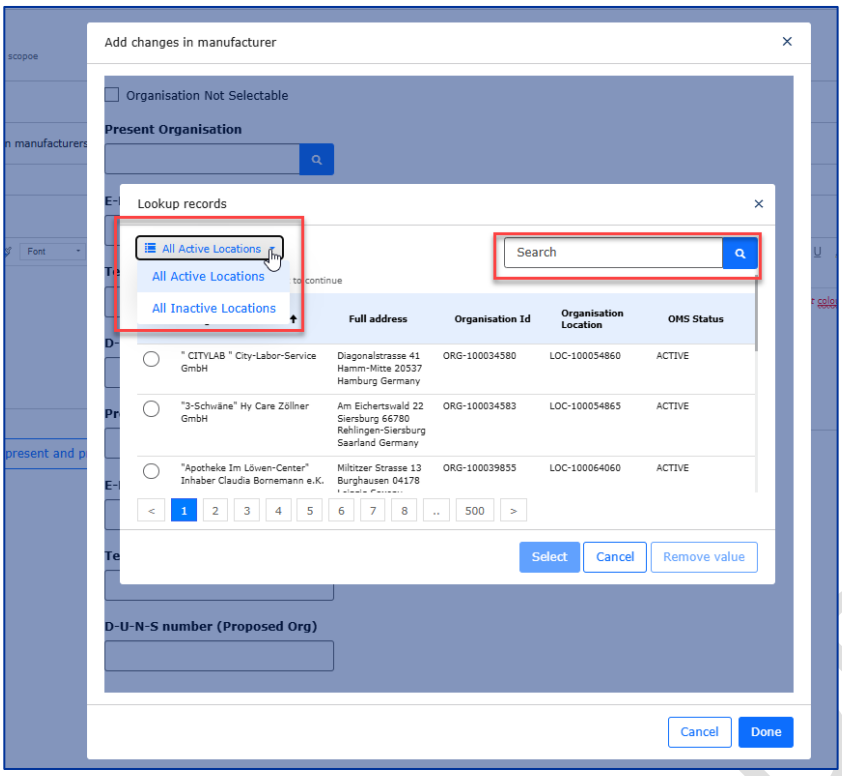


Figure 87 - Select Present Organisation

4. If you cannot find the Present organisation from OMS, as it no longer exists or there is a change in the organisation name which does not affect the address, or for example the organisation 'being deleted' is not available in OMS, it is possible to add Present organisation details **manually**. Please ensure that you have searched OMS (both inactive and active locations) before providing free text address in this field.

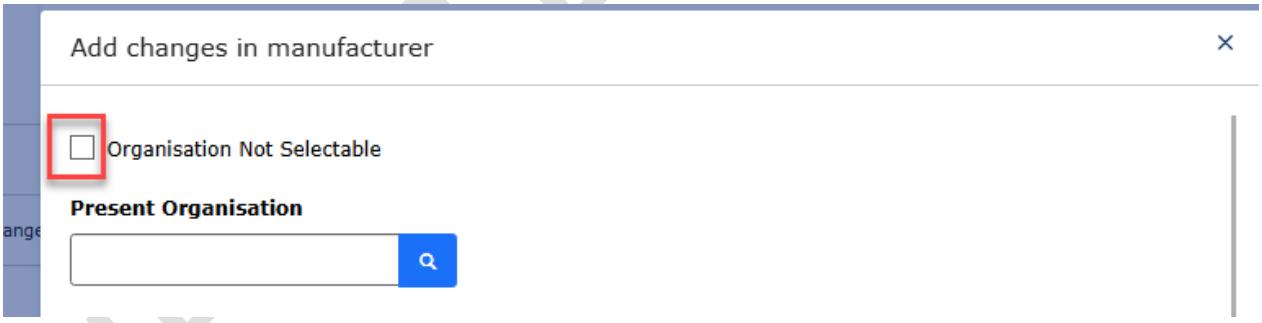


Figure 88 - Organisation Not Selectable

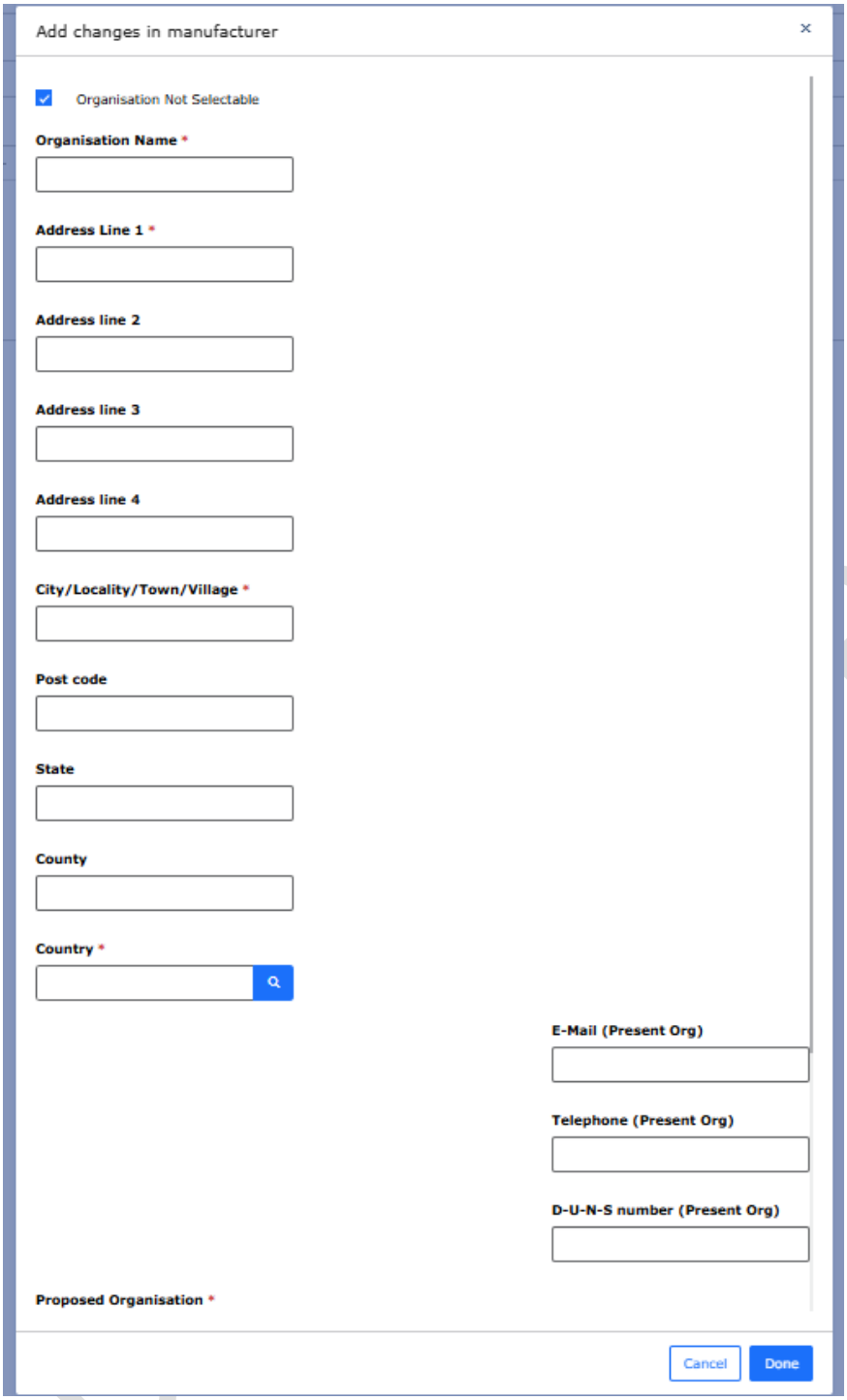


Figure 89 - Data of Not Selectable Organisation

5. Add the details of the present organisation in the free text fields (**only** if the organisation is **not** available in OMS.
6. Launch the OMS search for the Proposed organisation. The **Proposed organisation must be selected from OMS**. If the organisation is not available or the values are not correct, please update OMS first and then return to the application.

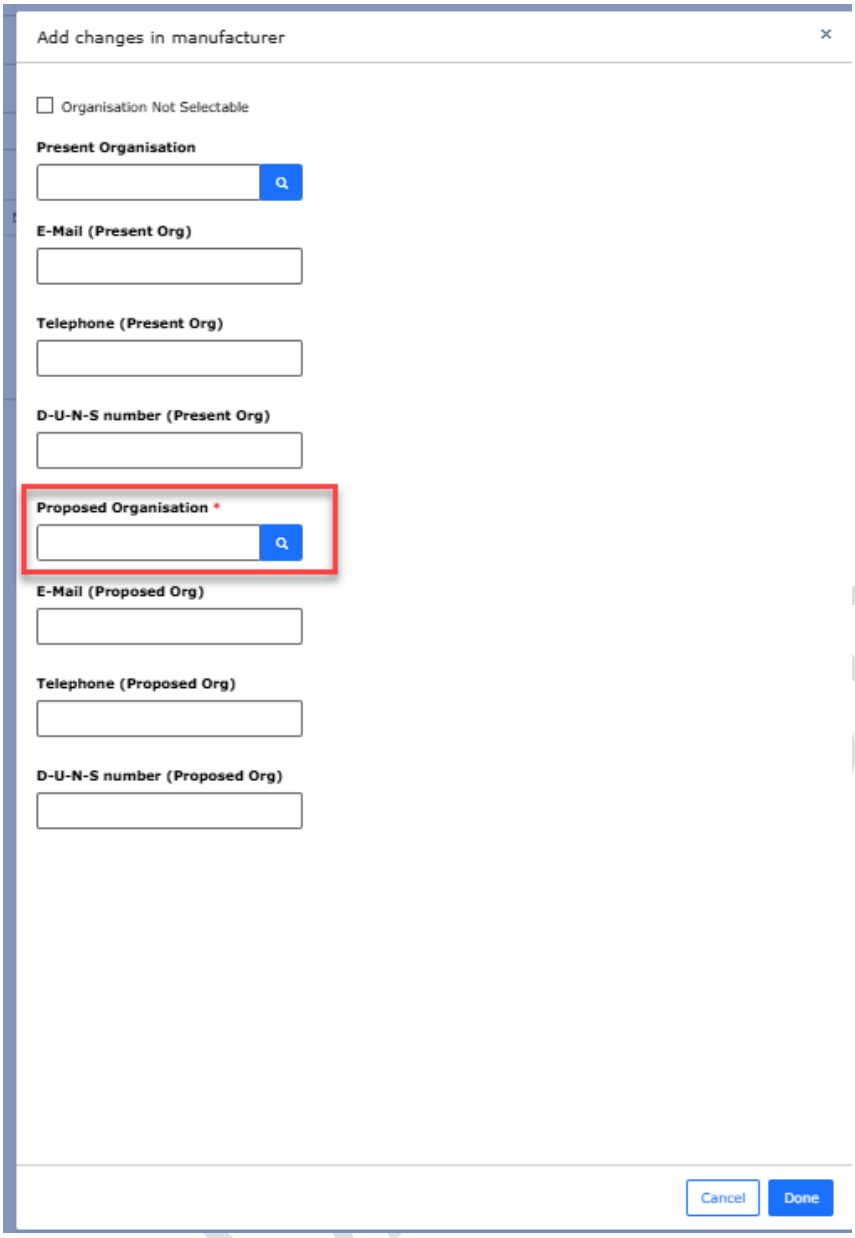


Figure 90 - Proposed Organisation

7. Select the organisation and press on the Done button.
8. When present (where relevant) and proposed organisations have been selected, press the Save button to return to the Present and Proposed section to add the textual changes.

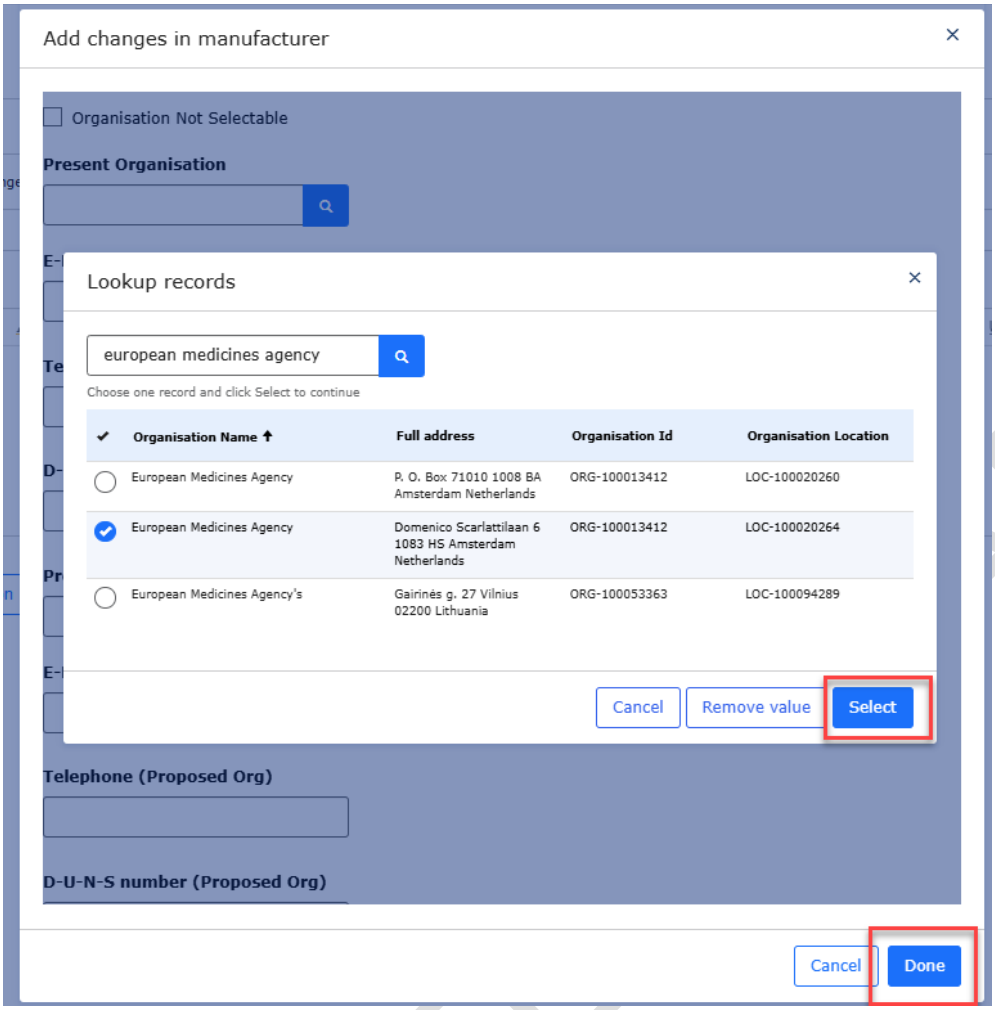


Figure 91 - Present and Proposed Section

9. Repeat the step to add all relevant organisation changes. This step can be repeated multiple times. More organisations can be added using the Add button or already selected organisations can be edited or deleted using the arrow on the right. It is possible to add multiple different organisations in the Proposed section without adding organisations in the Present section.

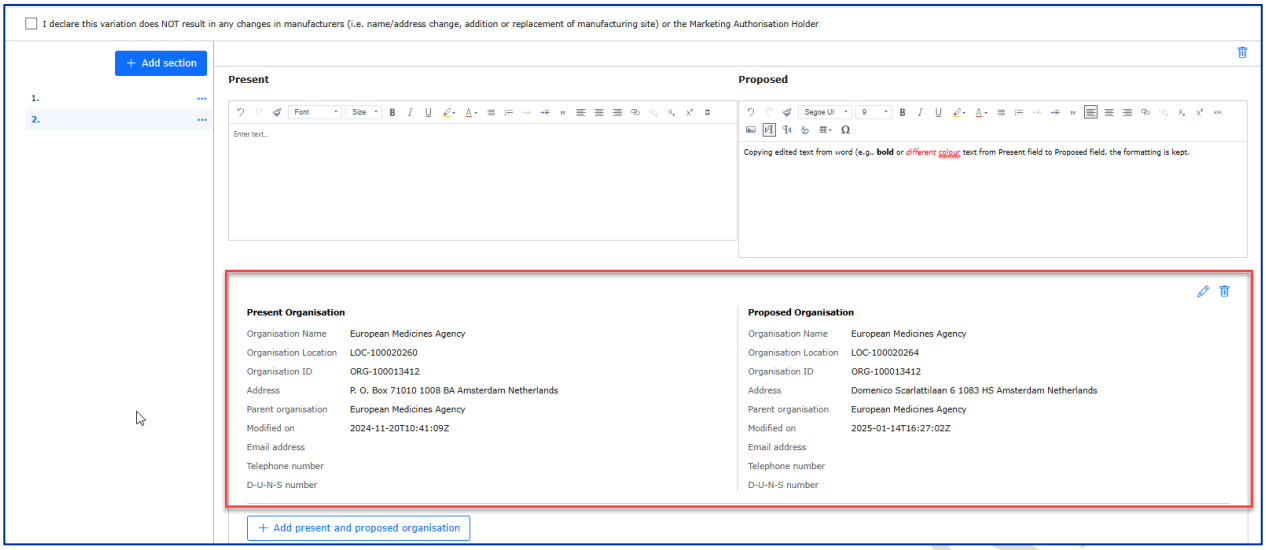


Figure 92 - Present and Proposed Value(s)

2.5.3. Add Package to an Existing Product

NOTE: this feature **does not** include the new pack sizes/packages in PMS. For CAPs the new packages will become available in the eAF upon approval of the variation. For non-CAPs the new packages will become visible in the eAF upon submission of this information in xEVMPD. Please note that the requirement to submit to eEVMPD is still valid also for CAP products.

2.5.3.1. Adding new pack size to a product that has only 1 existing package (pack-size)

1. In order to add a package to an existing product, navigate to the "Present and proposed Changes" section, then choose "Add Changes" to fill in the details.
2. Subsequently, select the scope for proposed changes to proceed.

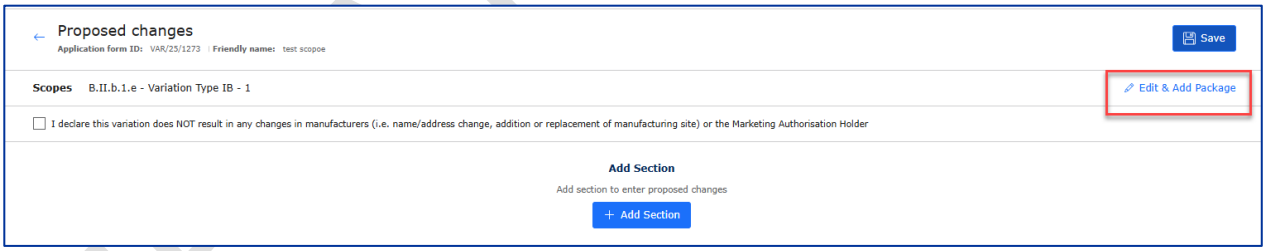


Figure 93 – Edit & Add Package

3. Fill in details in 'Present and Proposed Value(s)' tab
4. Select 1 scope (for example B.II.e.5.a)
5. Select the tab "Selected Medicinal Product(s)."
6. Please note that it is not necessary to select the medicinal product before opening the pop-up. Note that for medicinal products that have only existing 1 pack size, the package medicinal product is **automatically** selected. This automatically selected packaged medicinal product needs to be **unselected** after the new package has been added.

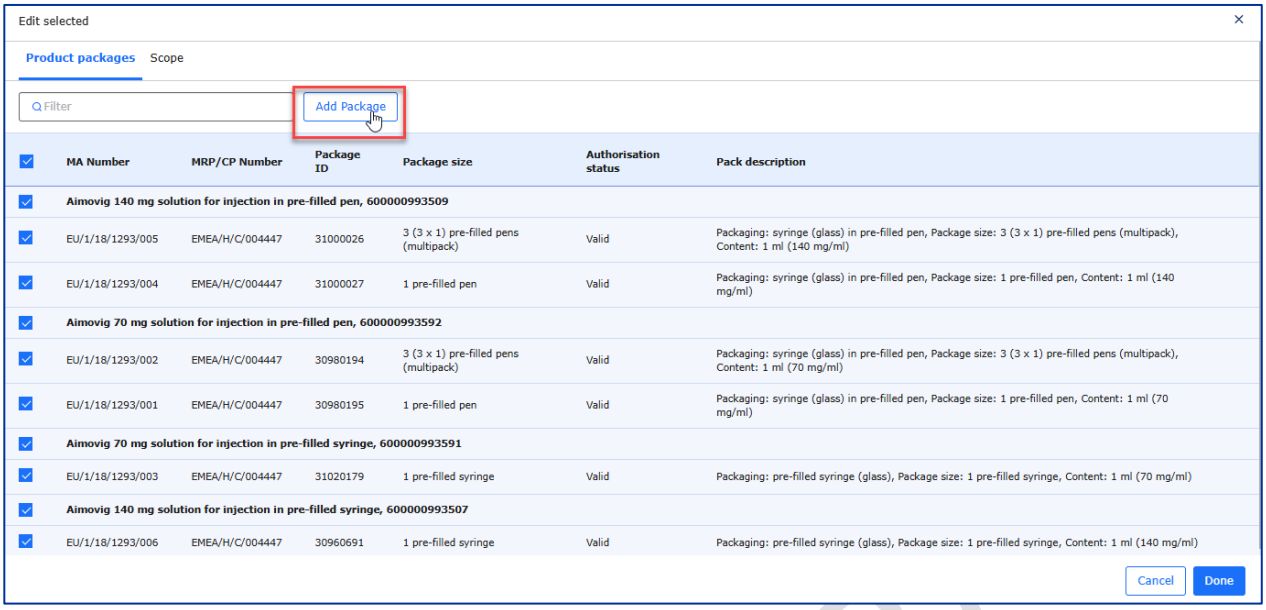


Figure 94 - Add Package

Figure 95 - Add Package Details

7. Click the option "add package", this will open a pop up window to include the details for the new pack size

8. Select the 'Parent Medicinal Product'. If you have more than 1 medicinal product and you wish to add a package to each medicinal product, you will need to repeat this step. It is not possible to select multiple medicinal products at one go. Please note that it is not necessary to select the medicinal product from the list before you open the pop up, the medicinal product for which the package will be added is the one selected in the pop-up.

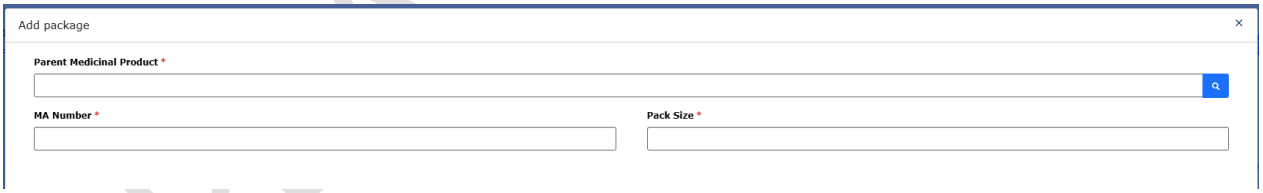


Figure 96 - Parent Medicinal Product Selection

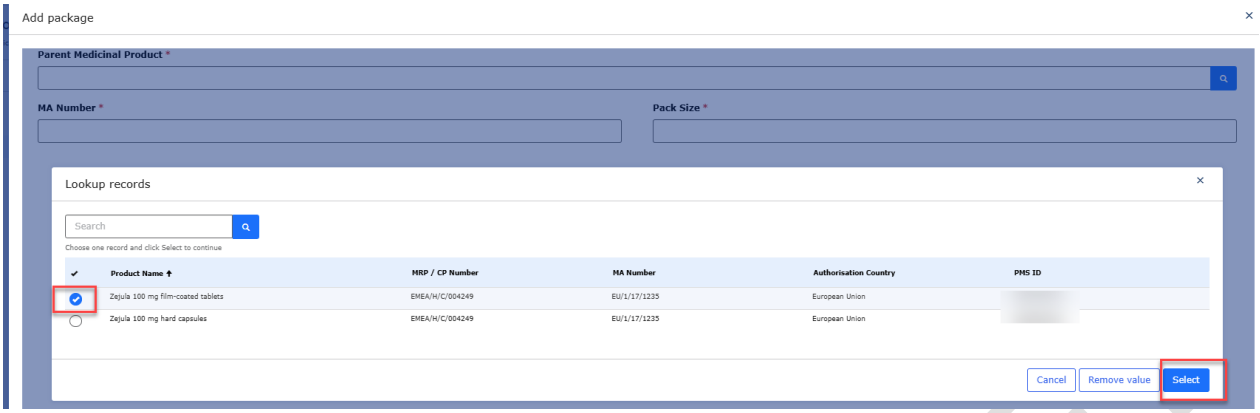


Figure 97 - Parent Medicinal Product Selection

9. Type the 'proposed' MA number for the new presentation (pack size) in the MA number field, if you only have one existing presentation, it is possible that you could 'guess' which one the new presentation will be given, alternatively, you can simply enter 'to be confirmed' or the root MA number into the field, for example: EU/1/123/1234/00X

10. Enter the pack size details in the Pack Size field and click 'Submit'

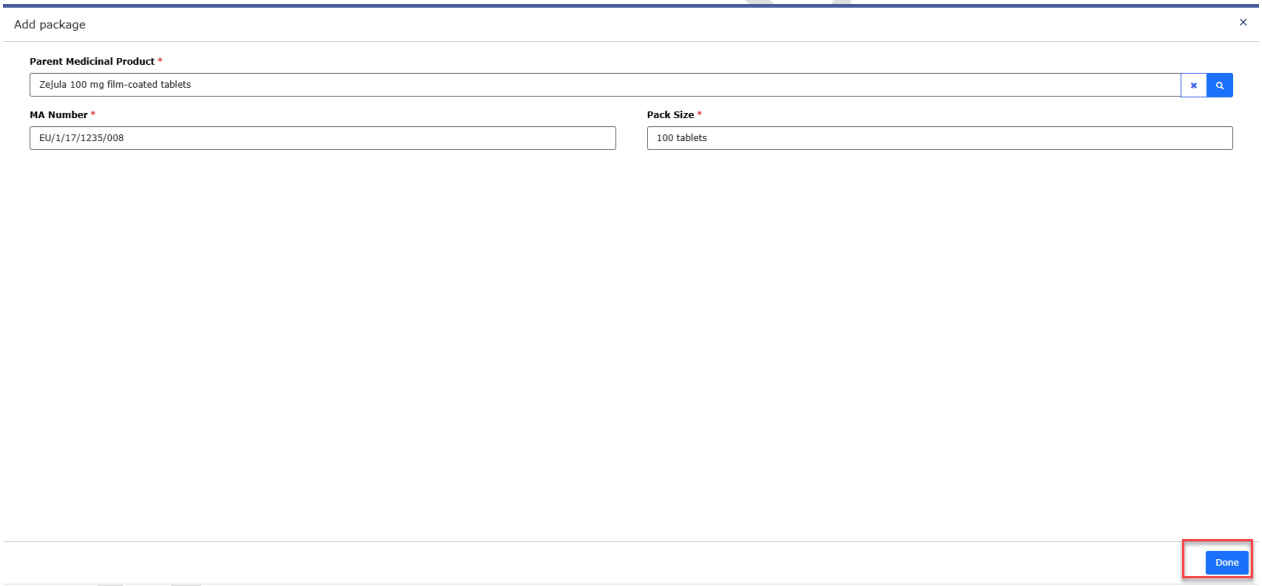


Figure 98 - Add Package Submission

11. You can now see the newly added pack size in the list of packaged medicinal products.

12. As the existing package is auto selected, it is important to untick the existing pack size (shown with the green arrow). As the change is to add the new pack size, we need to remove the existing pack size from the scope of this change.

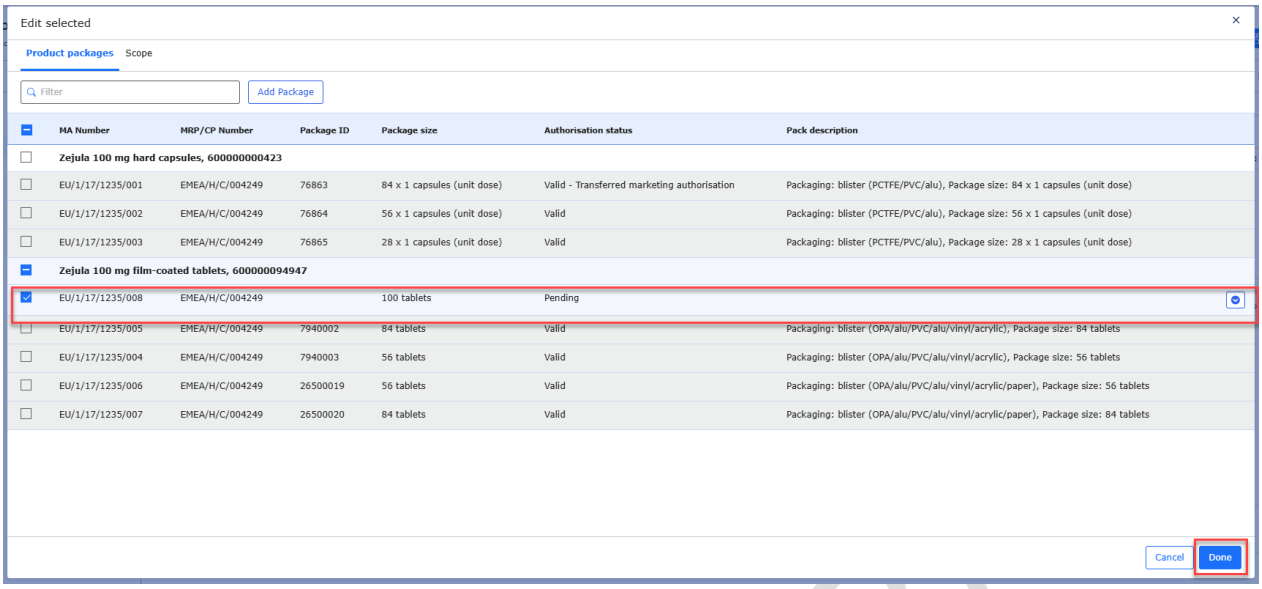


Figure 99 - Unticking the Existing Pack Size

13. Proceed to save the change.
14. You can now navigate back to the product selection section where you can see the new 'pending' entry added.

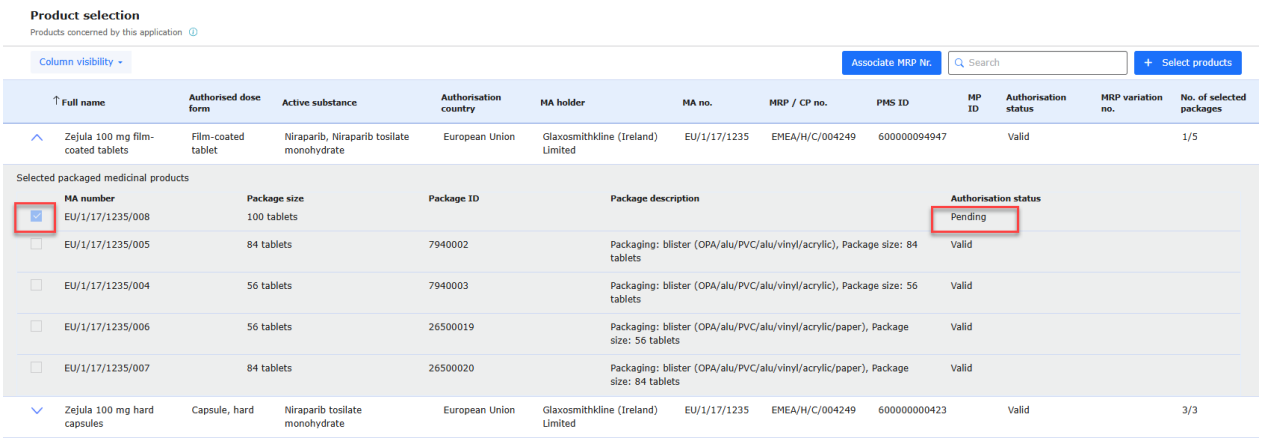
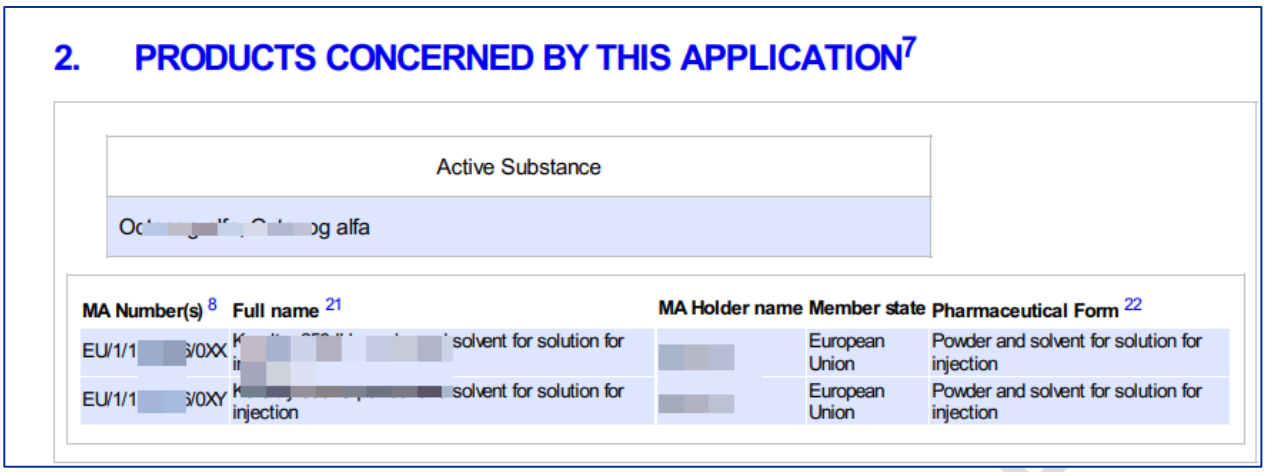


Figure 100 - Pending Entry

15. If you have more medicinal products for which you wish to add a pack size, you simply repeat the steps above.
16. When the pdf is generated, you can see the newly added pack size details, generated in section 2 (like you would have entered them manually in interactive pdf eAF in section 2).



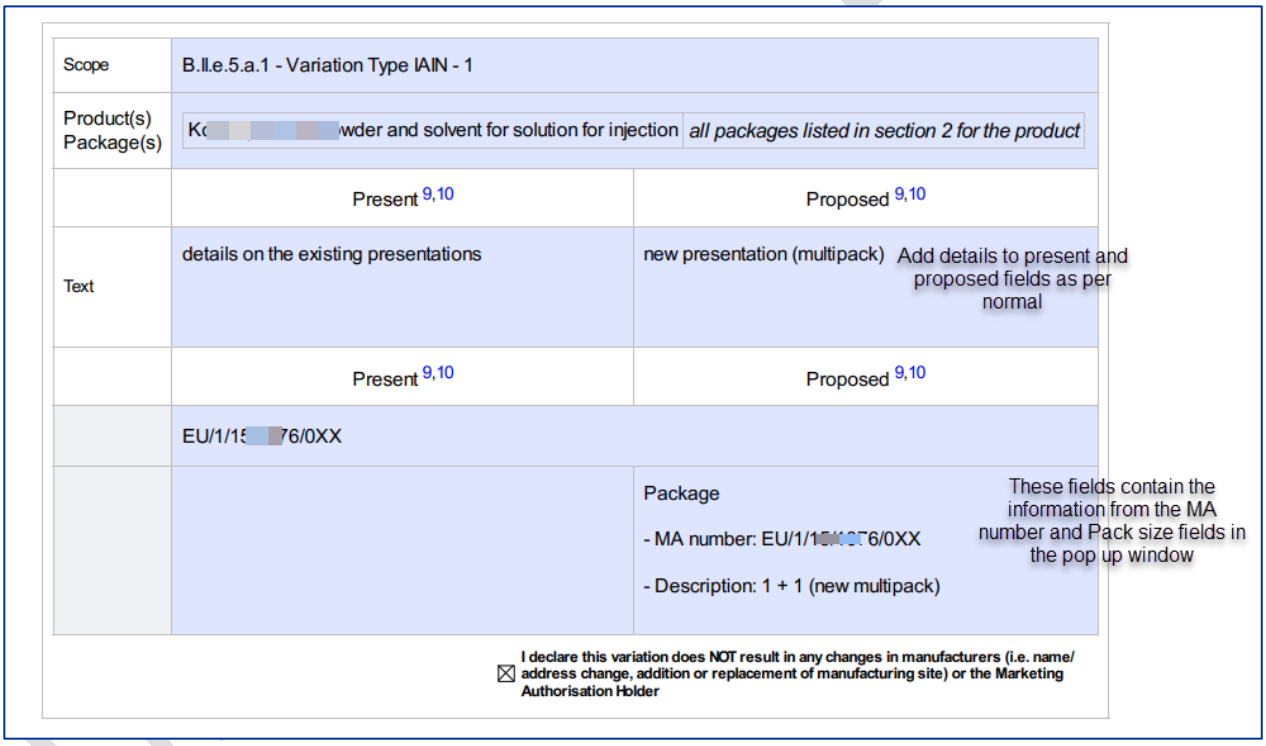
2. PRODUCTS CONCERNED BY THIS APPLICATION[7]

Active Substance
Oc[redacted]og alfa

MA Number(s) [8]	Full name [21]	MA Holder name	Member state	Pharmaceutical Form [22]
EU/1/1[redacted]/0XX	K[redacted] solvent for solution for i[redacted]	[redacted]	European Union	Powder and solvent for solution for injection
EU/1/1[redacted]/0XY	K[redacted] solvent for solution for injection	[redacted]	European Union	Powder and solvent for solution for injection

Figure 101 - Products Concerned by the Application

17. In the section 3 (present and proposed) of the pdf, you will see the information you filled in the present and proposed fields and additionally, the MA number and pack size details you entered in the 'add package' pop up window.



Scope	B.II.e.5.a.1 - Variation Type IAIN - 1	
Product(s) Package(s)	K[redacted]wder and solvent for solution for injection	*all packages listed in section 2 for the product*
	Present [9,10]	Proposed [9,10]
Text	details on the existing presentations	new presentation (multipack) Add details to present and proposed fields as per normal
	Present [9,10]	Proposed [9,10]
	EU/1/15[redacted]76/0XX	
		Package - MA number: EU/1/15[redacted]76/0XX - Description: 1 + 1 (new multipack) These fields contain the information from the MA number and Pack size fields in the pop up window

☒ I declare this variation does NOT result in any changes in manufacturers (i.e. name/ address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder

Figure 102 - Information Summary

2.5.3.2. Adding new pack size(s) to a product that has more than 1 existing pack size

1. In order to add a package to an existing product, navigate to the "Proposed Changes" section, then choose "Present and Proposed Changes".
2. Subsequently, click on "Add Present/Proposed" to proceed with this action.

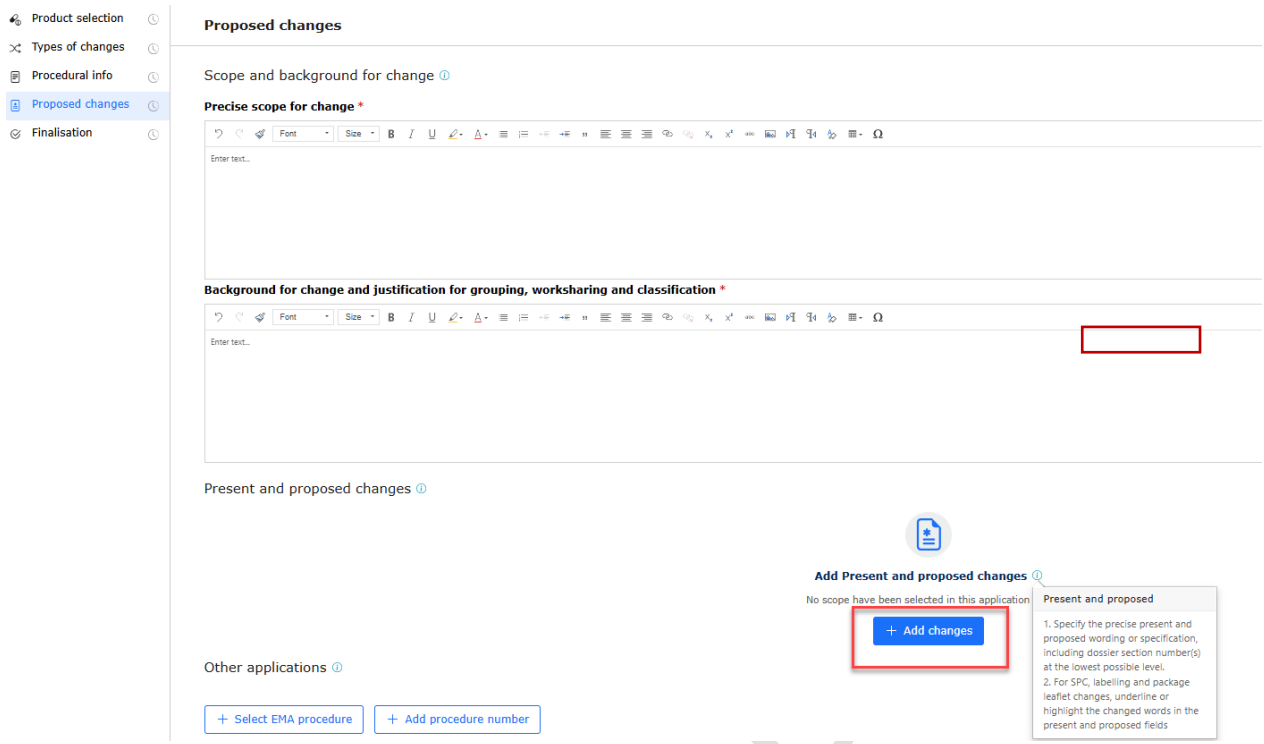


Figure 103 - Add Present and Proposed

18. Fill in details in 'Present and Proposed Value(s)' tab

19. Select **1 scope** (for example B.II.e.5.a) **at the time** to link with the new pack size (presentation). The other scopes will need to be linked to presentations in separate, repeated steps.

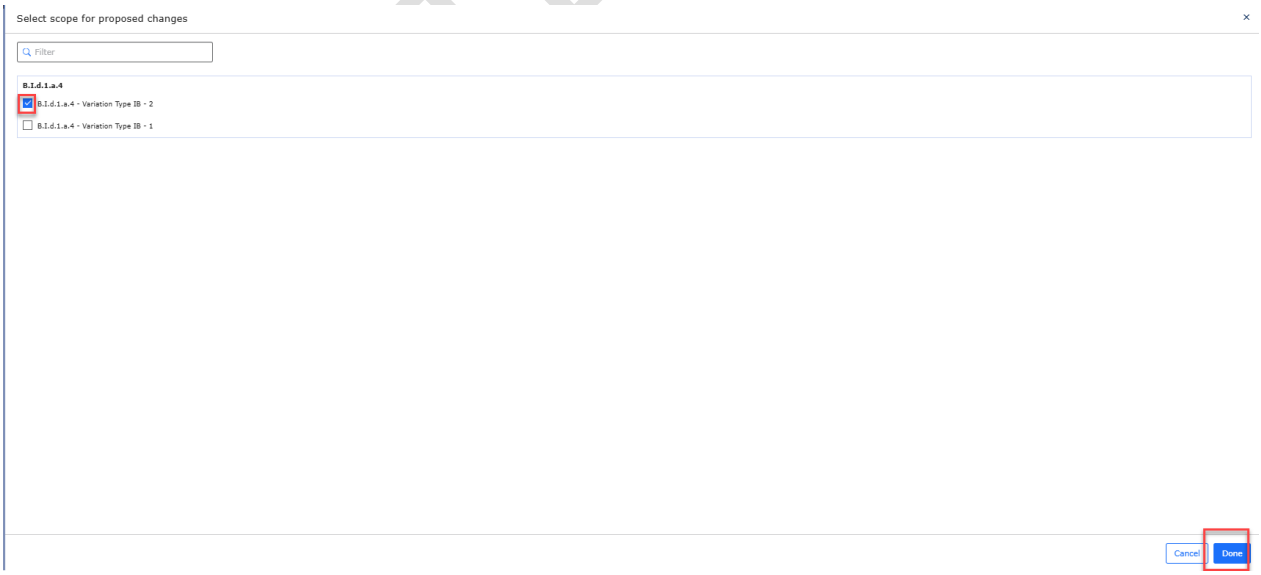


Figure 104 - Scope Selection

20. Select the tab "Selected Medicinal Product(s)."

21. Select the medicinal product in the pop-up window ; the currently approved presentations (pack sizes) are listed under the section packaged medicinal product.

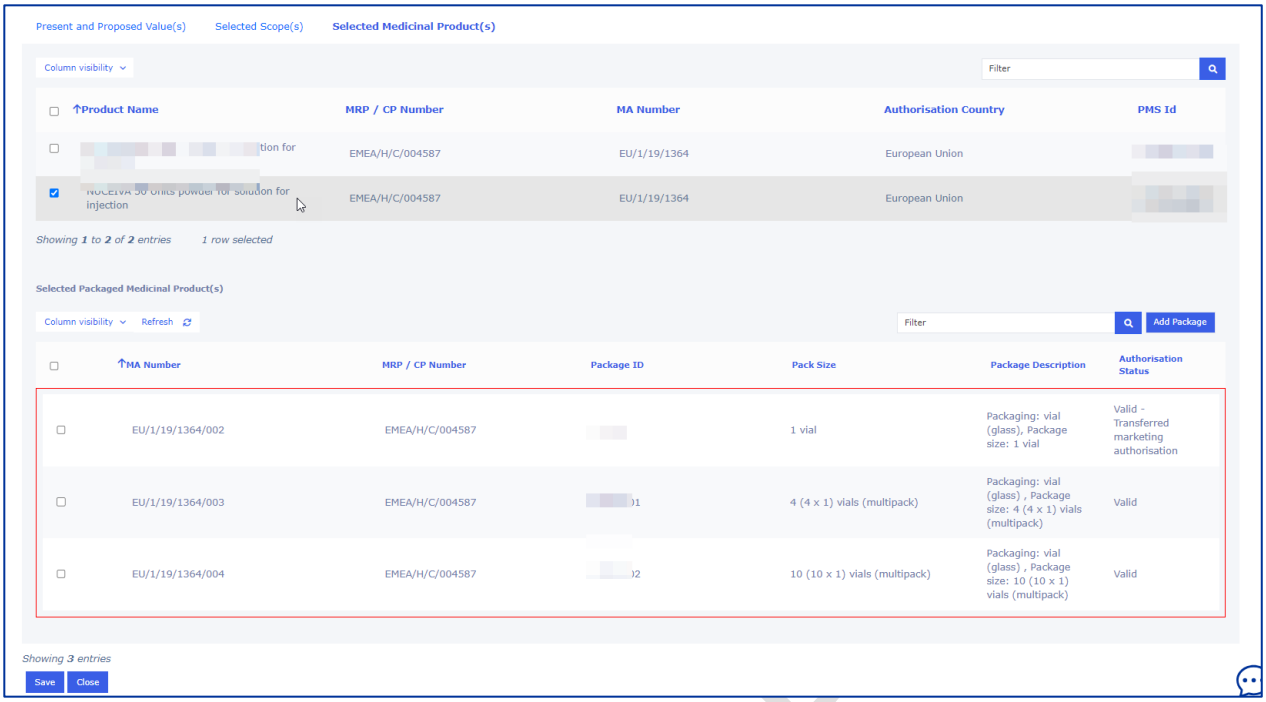


Figure 105 - Pop-up Window

22. Click the option "add package", this will open a pop up window to select the parent medicinal product and to include the details for the new pack size

23. Select the 'Parent Medicinal Product'. If you have more than 1 medicinal product and you wish to add a package to each medicinal product, you will need to repeat this step. It is not possible to select multiple medicinal products at one go.

24. Type the 'proposed' MA number for the new pack size in the MA number field, in some cases, it is possible that you could 'guess' which one the new presentation will be given, alternatively, you can simply enter 'to be confirmed' or the root MA number into the field for example: EU/1/123/1234/00X.

25. Enter the pack size details in the pack size field and click 'Submit' button.

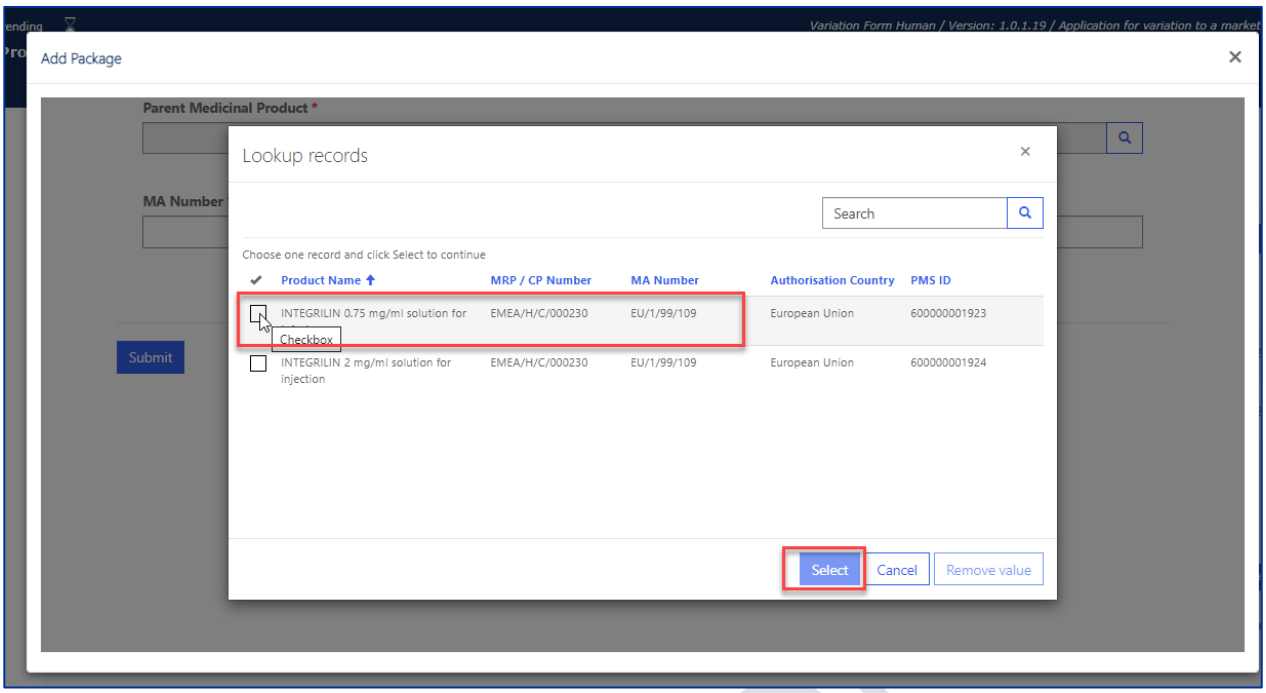


Figure 106 - Lookup Records

26. You can now see the newly added pack size in the list of packaged medicinal products.

27. If you wish to delete the new draft package, you can click delete and repeat the step to add it again

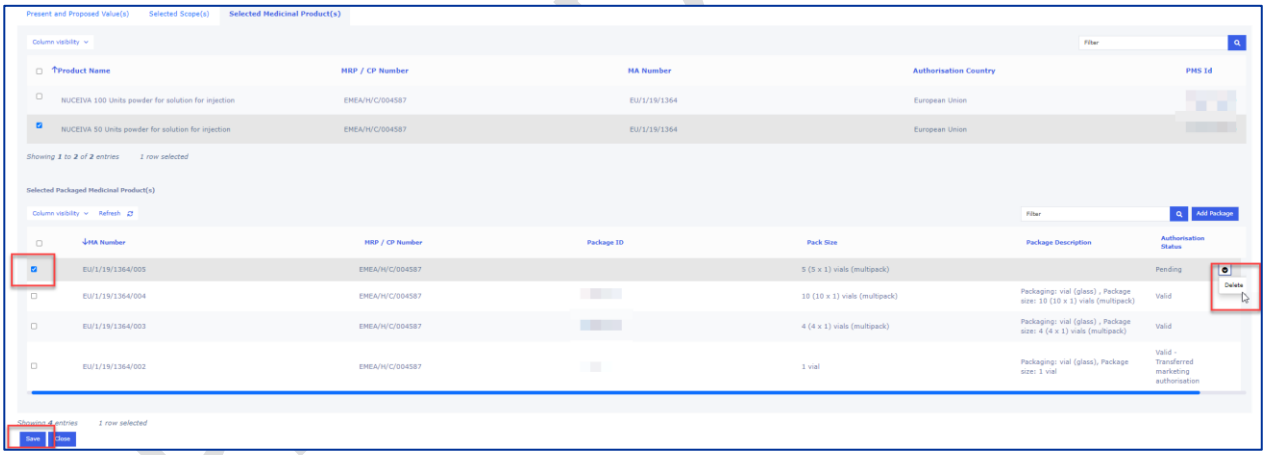


Figure 107 - Save Draft Package

28. Proceed to save the change.

29. Repeat all the steps; add the details of the change in present and proposed fields, select the next scope and create another pack size as needed. For a grouping of variations, proceed to link the scopes and the presentations as per normal.

Figure 108 - Select Scope

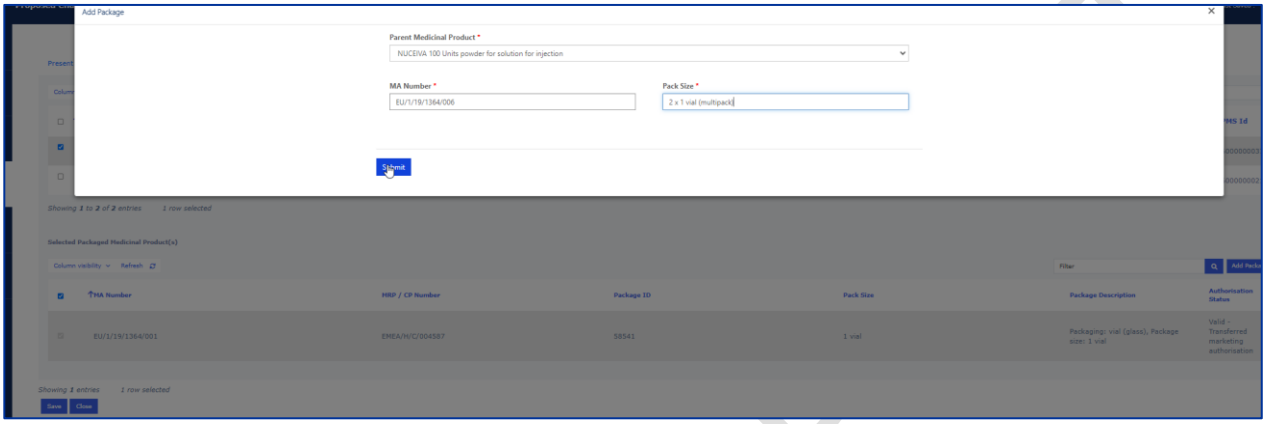


Figure 109 – Add Package Submission

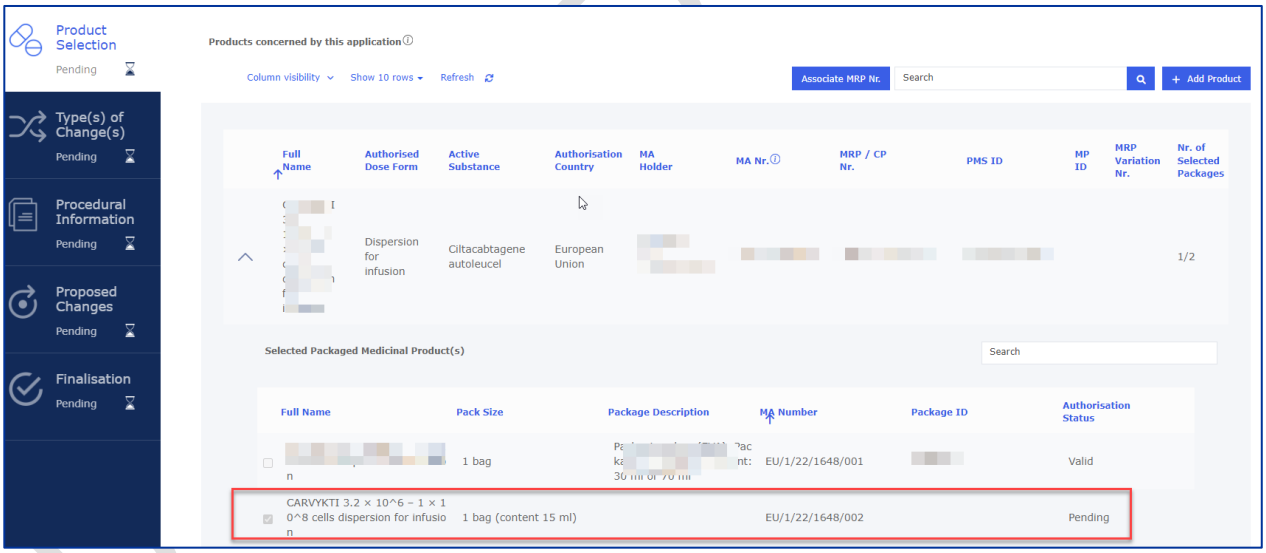
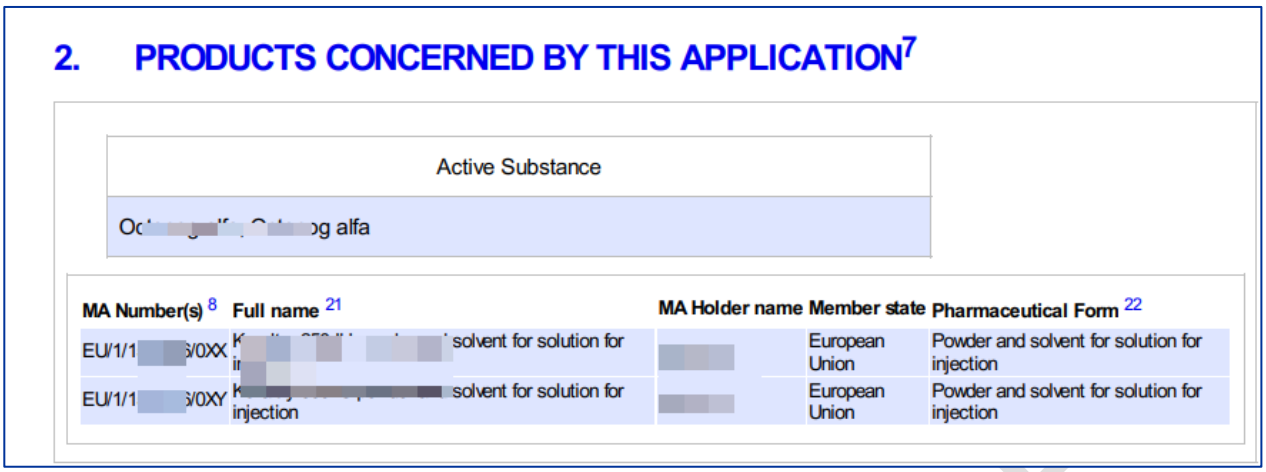


Figure 110 - Pending Submission

30. If you have more medicinal products for which you wish to add a pack size, you simply repeat the steps above.

31. When the pdf is generated, you can see the newly added pack size details, generated in section 2 (like you would have entered them manually in interactive pdf eAF in section 2).



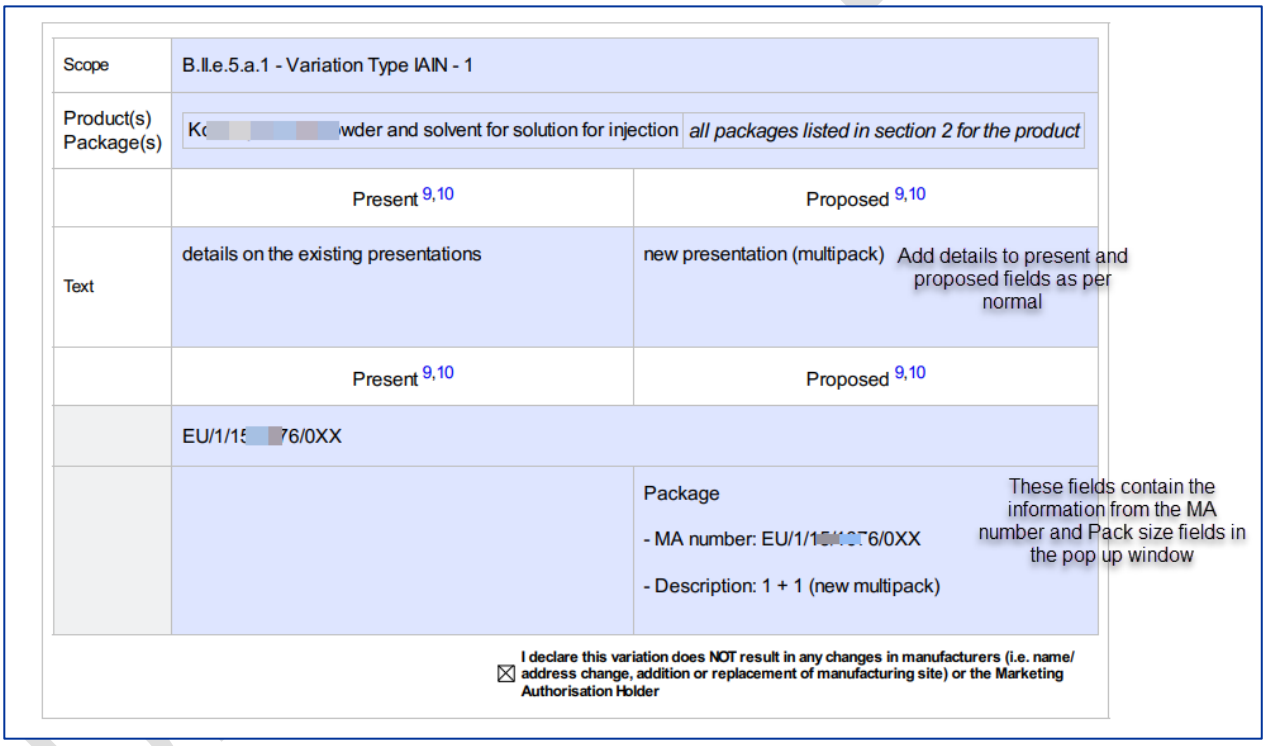
2. PRODUCTS CONCERNED BY THIS APPLICATION[7]

Active Substance
Oc[redacted]g alfa

MA Number(s) [8]	Full name [21]	MA Holder name	Member state	Pharmaceutical Form [22]
EU/1/1[redacted]/0XX	K[redacted] solvent for solution for i[redacted]	[redacted]	European Union	Powder and solvent for solution for injection
EU/1/1[redacted]/0XY	K[redacted] solvent for solution for injection	[redacted]	European Union	Powder and solvent for solution for injection

Figure 111 - Products Concerned by the Application

32. In section 3 (present and proposed) of the pdf, you will see the information you filled in the present and proposed fields and additionally, the MA number and pack size details you entered in the 'add package' pop up window.



Scope	B.II.e.5.a.1 - Variation Type IAIN - 1	
Product(s) Package(s)	K[redacted]wder and solvent for solution for injection	*all packages listed in section 2 for the product*
	Present [9,10]	Proposed [9,10]
Text	details on the existing presentations	new presentation (multipack) Add details to present and proposed fields as per normal
	Present [9,10]	Proposed [9,10]
	EU/1/15[redacted]76/0XX	
		Package - MA number: EU/1/15[redacted]76/0XX - Description: 1 + 1 (new multipack) These fields contain the information from the MA number and Pack size fields in the pop up window

☒ I declare this variation does NOT result in any changes in manufacturers (i.e. name/ address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder

Figure 112 - Information Summary

2.5.3.3. Multiple change

Duplicating the Present and Proposed Fields

If you need to add more than one Present and Proposed field (equivalent to the section level + button in the interactive pdf form), you can do this by repeating the previous steps, i.e. clicking the Add Present/Proposed and selecting the organisation(s) and related text changes. This step can be repeated as many times as needed for each scope and product combination.

Linking of the organisations to the text changes

If you need to add more than one Present and Proposed field with related organisation(s) (equivalent to the higher level + button in the interactive pdf form), you can do this by repeating the previous steps, i.e. clicking the Add Present/Proposed and selecting the organisation(s) and related text changes. This step can be repeated as many times as needed for each scope and product. For example, you have one change related to the Manufacturer A you first select the impacted organisations and then add the text changes in Present and Proposed fields and link the scope and the selected medicinal products/Packaged medicinal products and then repeat the step to add the details of the Manufacturer B (select the organisations first and then add the text changes and link the (same or different) scope and medicinal products/Packaged medicinal products.

2.5.3.4. Structured changes

Note that currently 'Recommended Changes' column may indicate **non-relevant area of changes**, due to scopes being linked to many different types of changes. This will be addressed and improved in future releases.

2.5.3.4. Medical Device(s)

The medical device section can be added in the present and proposed section when the change concerns a medical device for example an addition or a change of an existing device.

1. Please ensure that you have ticked the 'Medical Device' tick box in Procedural Information section (Change(s) concern(s) section.

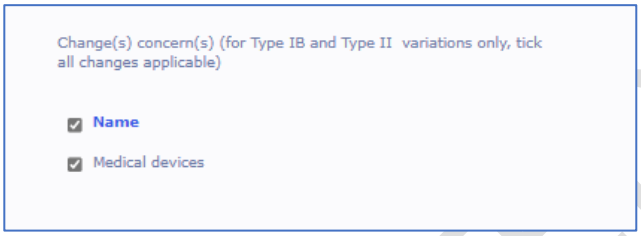


Figure 113 - Medical Device Box

2. To fill in the Medical Device(s) section, select the 'Add Present/Proposed

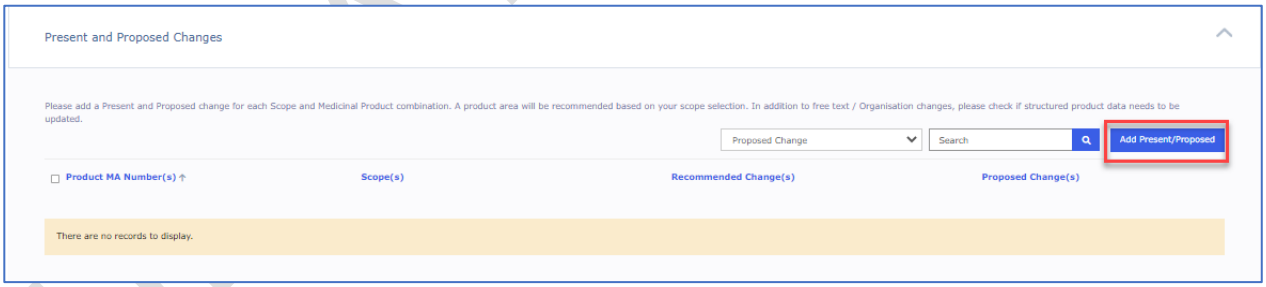


Figure 114 - Add Present/Proposed Changes

3. Select the scope and the medicinal product/presentations

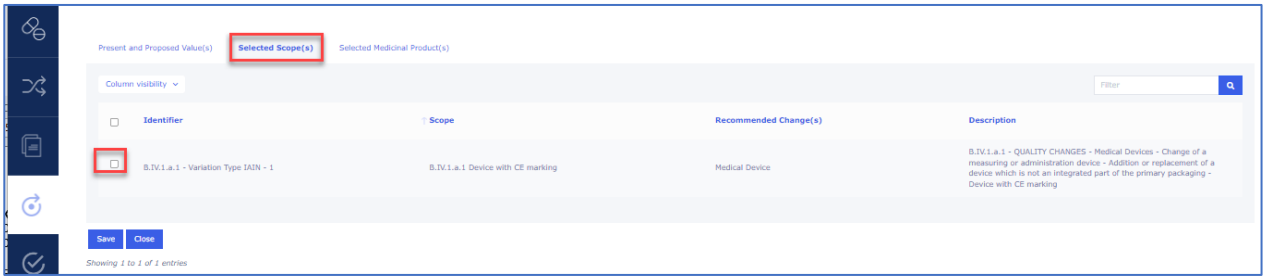


Figure 115 - Selected Scope(s)

4. When you return to 'Proposed Changes main section, select the relevant product/scope combination by using the tick box and select Medical Device from the dropdown menu. The product must be selected for the dropdown menu to **work**.

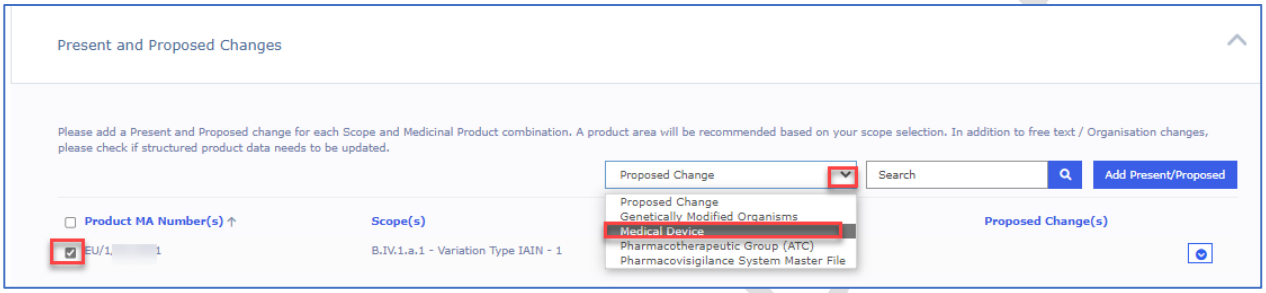


Figure 116 - Selection of Relevant Scope/Product Combination

5. The Medical Devices subsection (section 4d in the pdf form) will open. Please note that the 'present values' section will appear empty, and you will not be able to edit this information (as it is currently not available from PMS). To edit the section click Add Device and you will be able to make the selections as usual in this section.

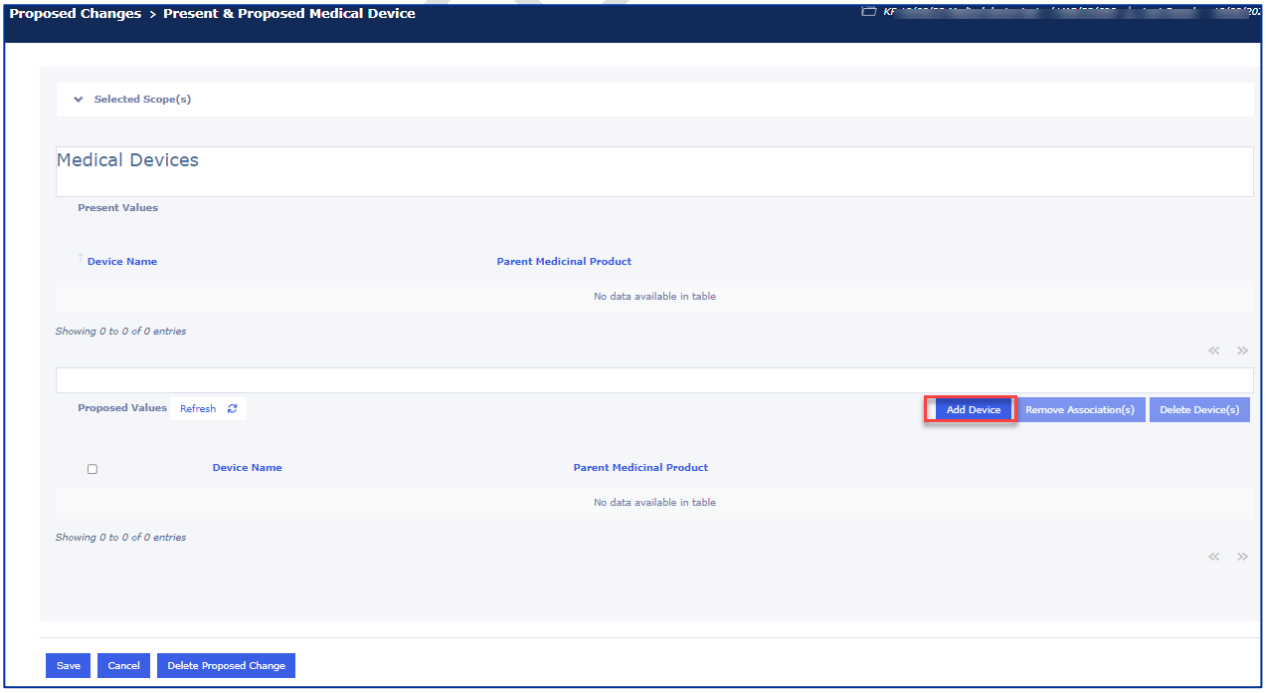


Figure 117 - Add Device

6. A new window will open with Accordion of different sections of the Medical Device and Companion Diagnostic. Please fill in each section, please note that information may be shown slightly differently as in the pdf, however, the content is the same.

Figure 118 - Medical Device and Companion Diagnostic

7. Select if the change is to change an existing device or to add a new device;

Figure 119 - Change Selection - Medical Device and Companion Diagnostic

8. Fill in the free text fields and selections to detail Device(s) identification and classification

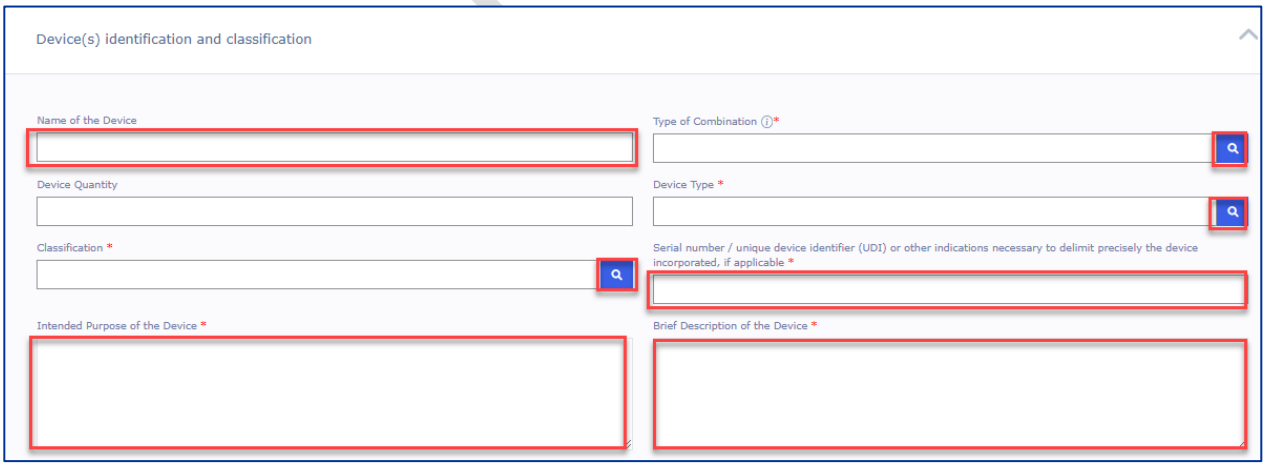


Figure 120 - Device(s) Identification and Classification

9. Manufacturer's function and the manufacturer of the Device is now selected (mandatorily) from OMS

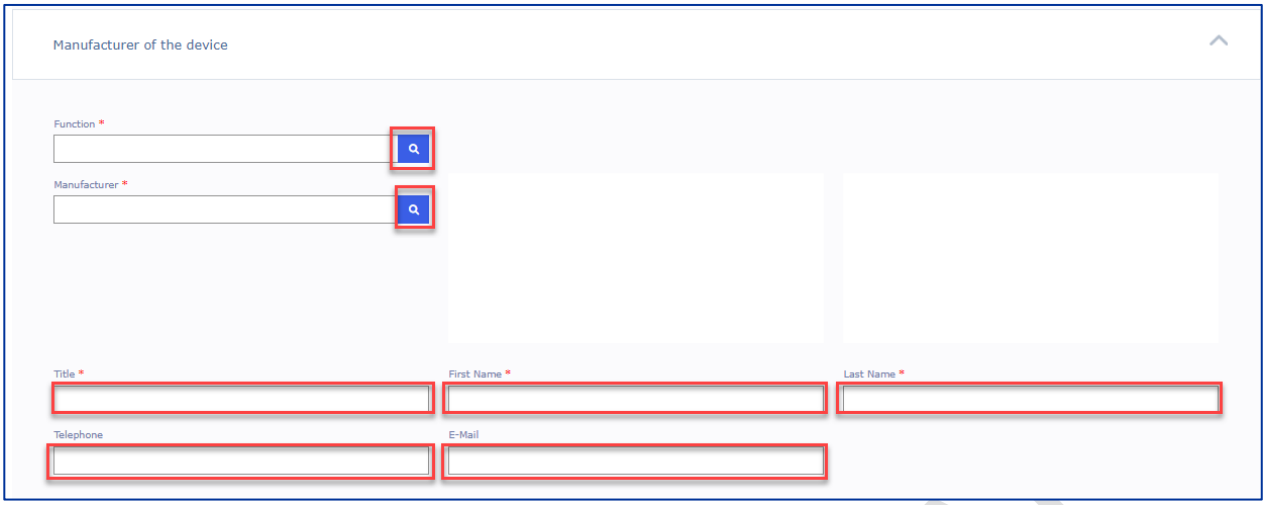


Figure 121 - Manufacturer of the Device

10. Proceed to fill in the rest of the sections

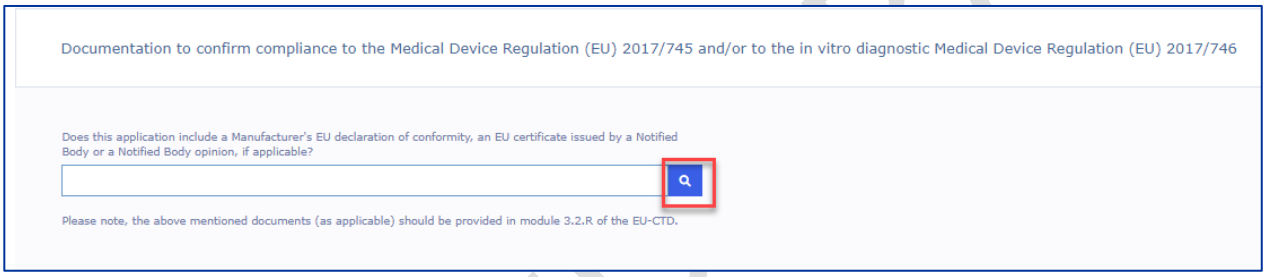


Figure 122 - Upload of Documentation

11. Notified body is also now selected from OMS

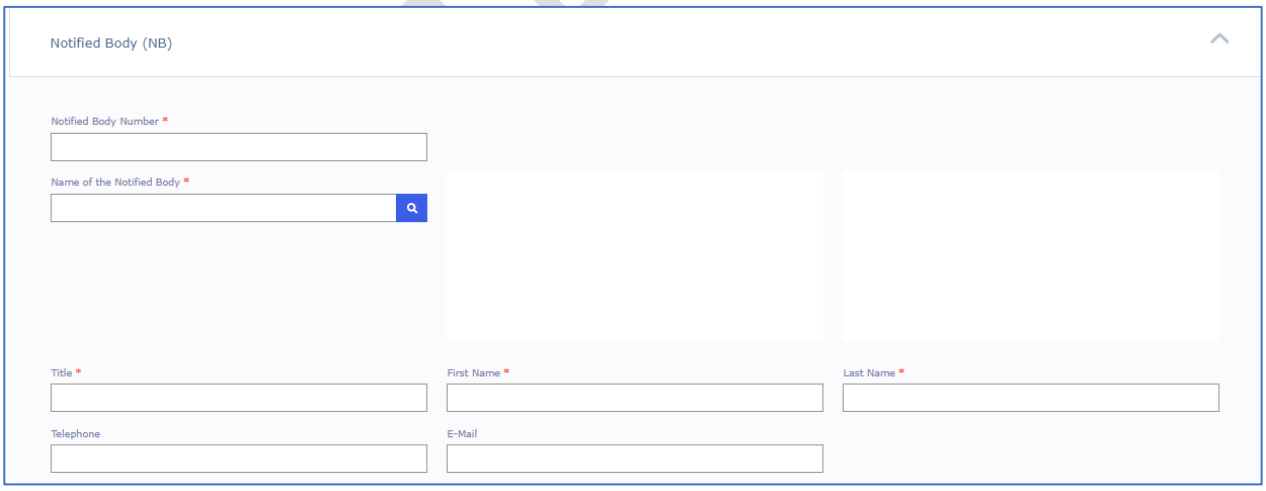


Figure 123 - Notified Body

2.5.3.5. ATC Code change

The ATC code change should be applied for all Medicinal Products (i.e. the change is on the Authorisation product level).

1. Select the relevant product by using the tick box, select Pharmacotherapeutic Group (ATC) from the dropdown menu and click on Add Present/Proposed. The product must be selected for the dropdown menu to **work**.

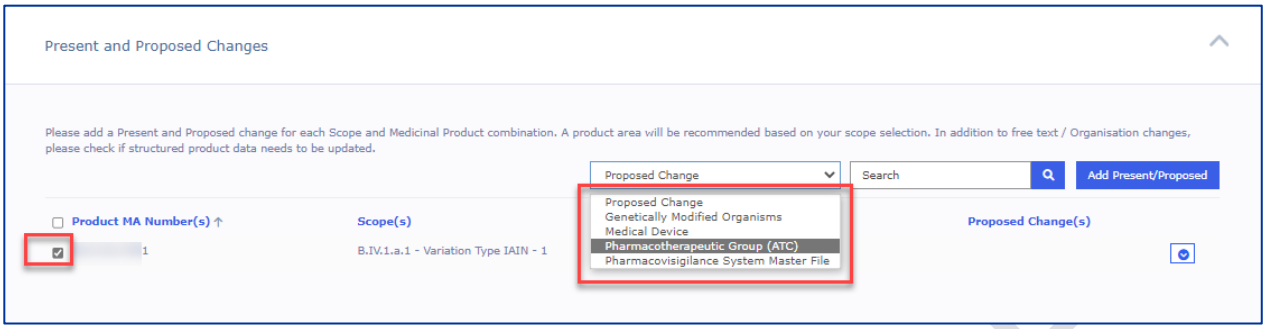


Figure 124 - Present and Proposed Changes

2. Under Proposed Values, click on the click on the Add button to enter the details of the ATC code change

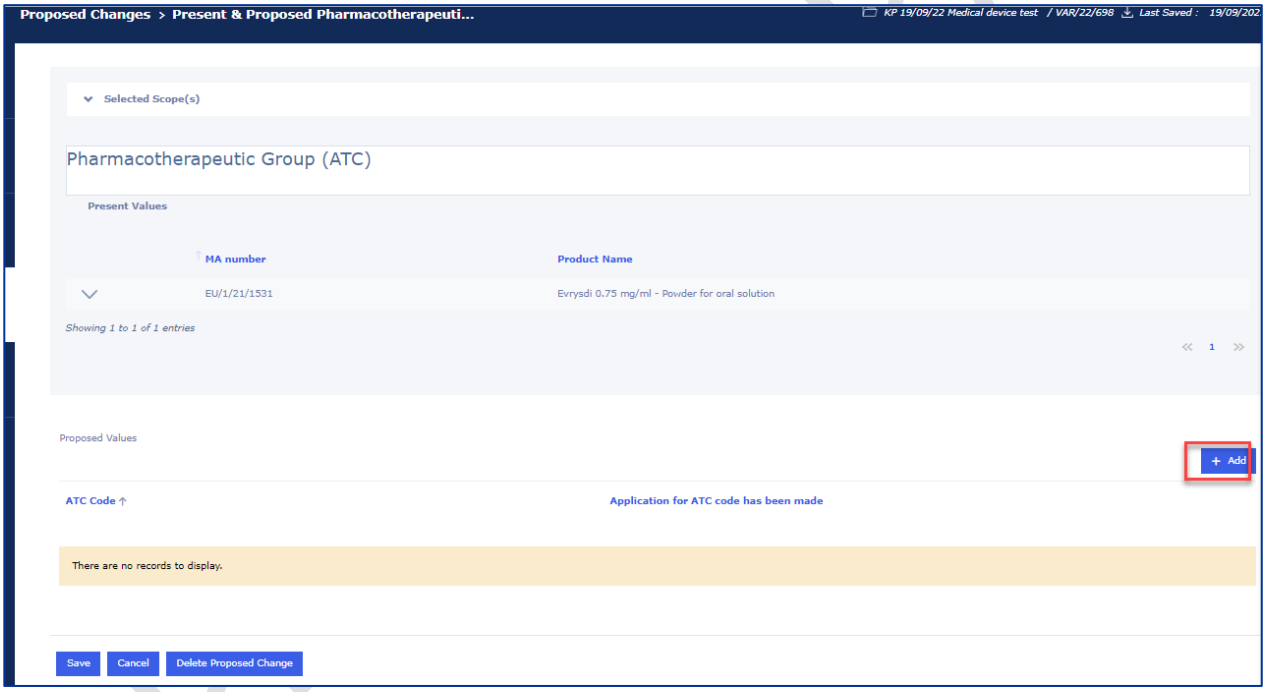


Figure 125 - ACT Code Change

The ATC code can currently only be searched using the active substance.

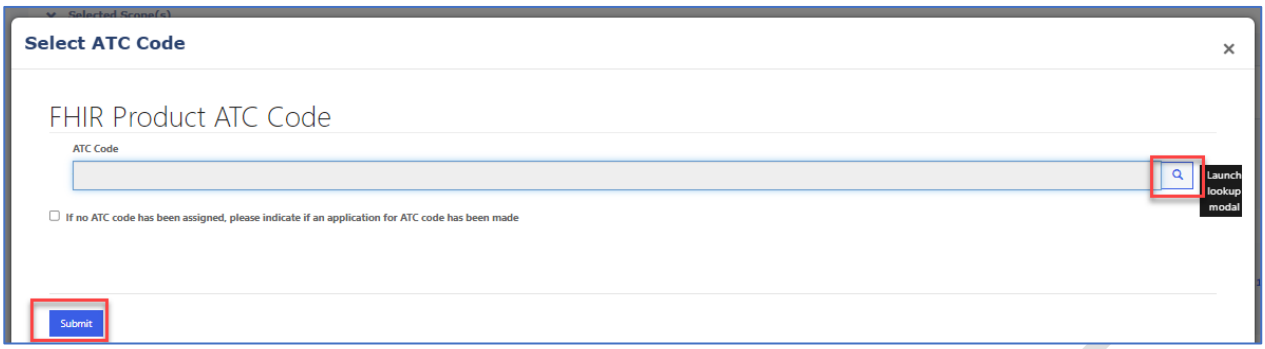


Figure 126 - Selection of ATC Code

3. Click on the Submit button and you will be taken back to the Proposed Changes main page
4. Click on the Save button to save your changes in the form

2.5.3.6. Pharmacovigilance System Master File

1. Select the relevant product by using the tick box and select 'Pharmacovigilance System Master File' (PSMF) from the dropdown menu (the typo in word Pharmacovigilance is a known issue). The product must be selected for the dropdown menu to work.

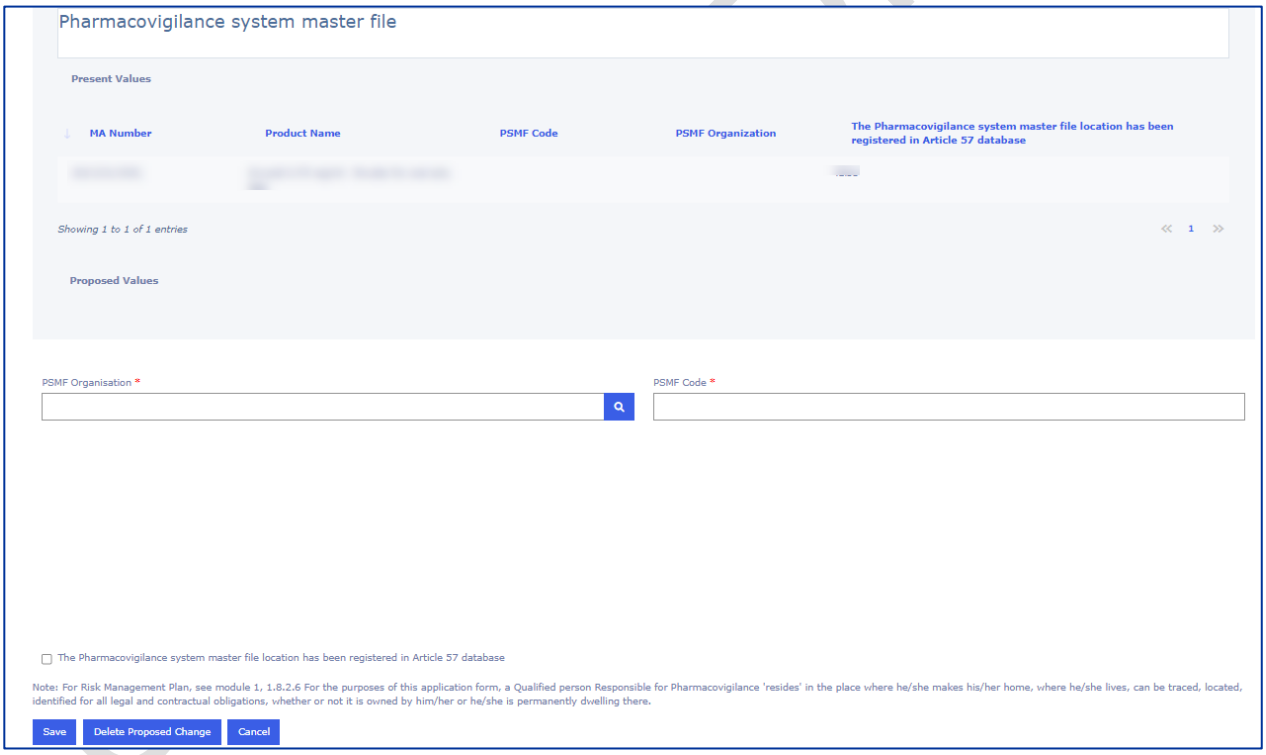


Figure 127 - Pharmacovigilance System Master File

2. Add the PSMF Organisation from the magnifying glass and the PSMF Code
3. Click on the Save button and you will be taken back to the Proposed Changes main page
4. Click on the Save button to save your changes in the form

2.5.3.7. Genetically Modified Organisms

1. Select the relevant product by using the tick box and select 'Genetically Modified Organisms Code' from the dropdown menu. The product must be selected for the dropdown menu to work.

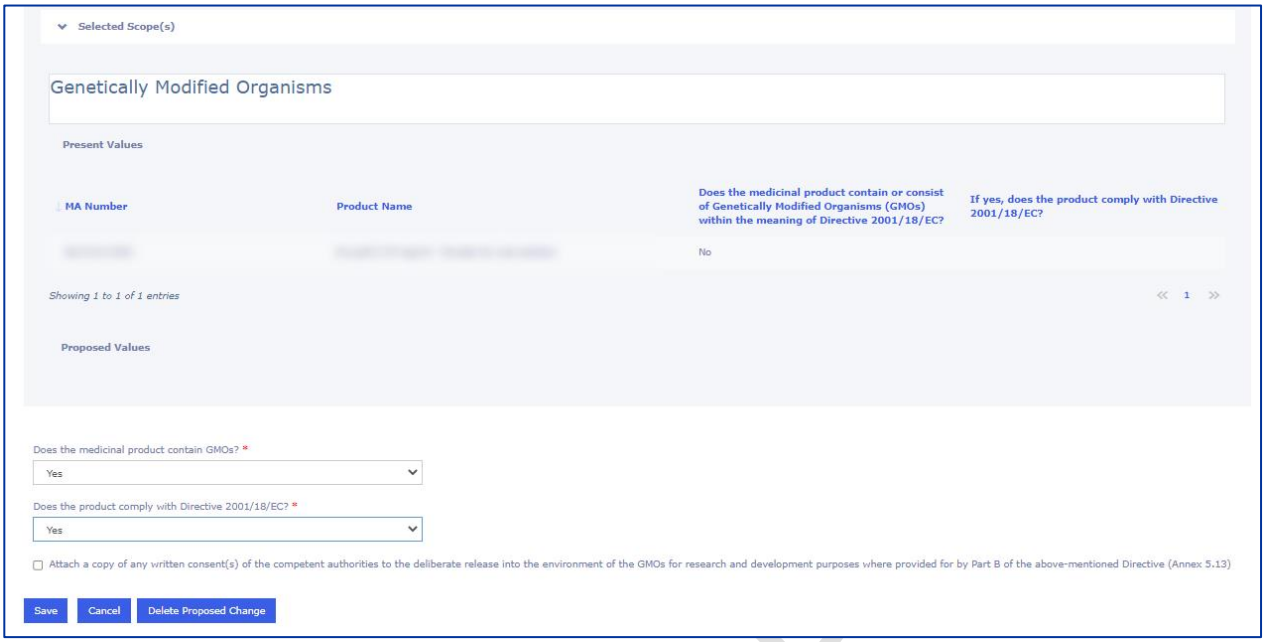


Figure 128 - Genetically Modified Organisms Code

2. Reply to the GMO-related enquiries
3. Click on the Save button and you will be taken back to the Proposed Changes main page
4. Click on the Save button to save your changes in the form

2.5.3.4. Other applications

NOTE: Other applications will appear in an incorrect (random) order on the web UI – i.e. they are not show in the order they were entered, however, they will appear in the order they were entered in the pdf output.

For Centralised procedure, you should be able to find related procedure numbers from the pre-generated list of procedures which is opened by clicking the Select EMA Procedure button. There is currently a known issue affecting this feature. If the procedure you wish to add is not available, please use the free text field opened by clicking the Add button.

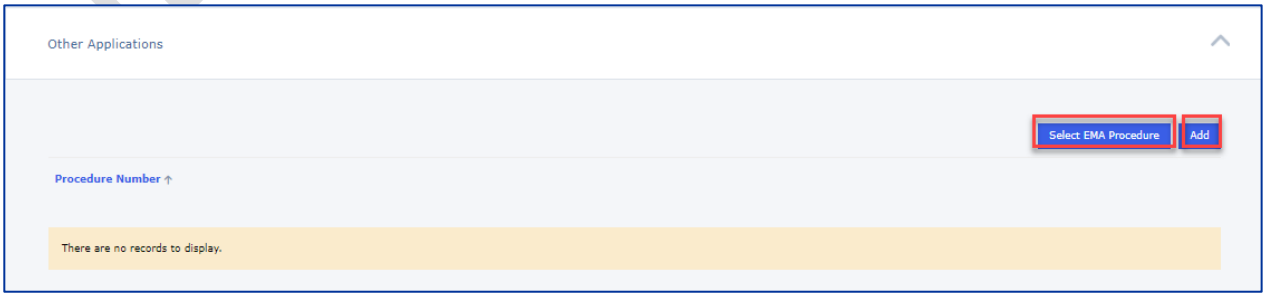


Figure 129 - Selection of EMA Procedure

2.6. Additional Information

The additional information section contains the sections 4a, 4b and 4c of the pdf eAF. These sections are only visible in the form depending on the previous selections in the form. Please note that there is a delay in calculating this information based on the procedure type and the product and it can take several minutes before these sections appear in the form.

Figure 130 - Additional Information Section

2.6.1. Type IB and Type II Variations – new indications – orphan medicinal product information

1. To launch the window to search and select the procedure, click the select button

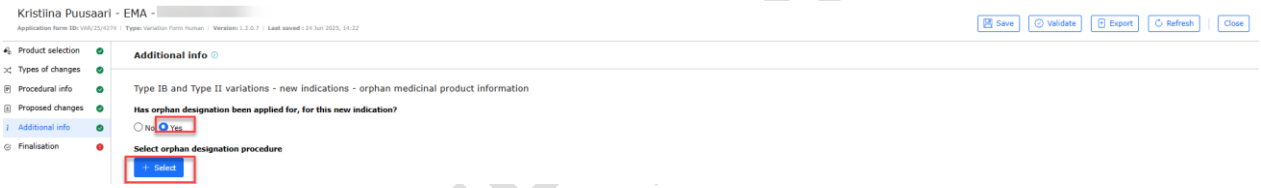


Figure 131 - Orphan Designation Procedure

2. This will launch a lookup window where additional filtering/search criteria can be used to find the relevant procedure

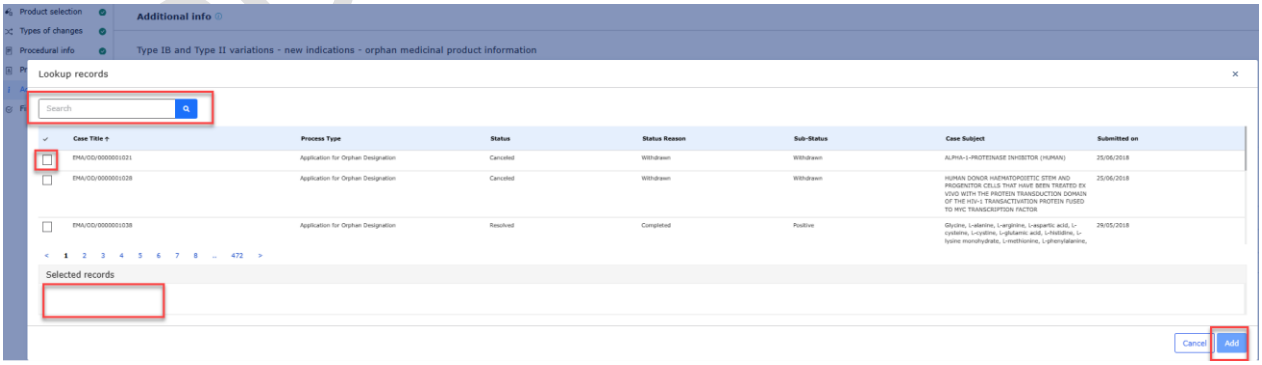


Figure 132 - Lookup Records

3. The rest of the fields are filled in automatically based on the information held in the database for the selected procedure

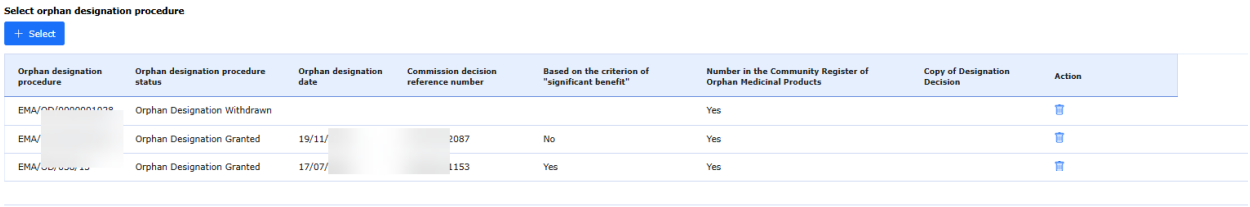
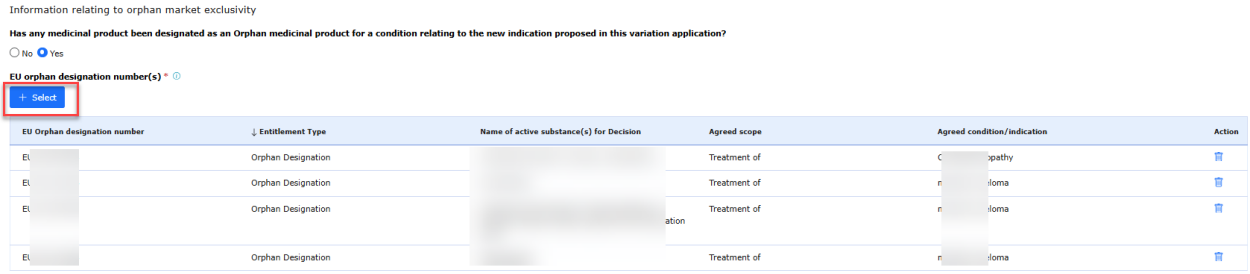


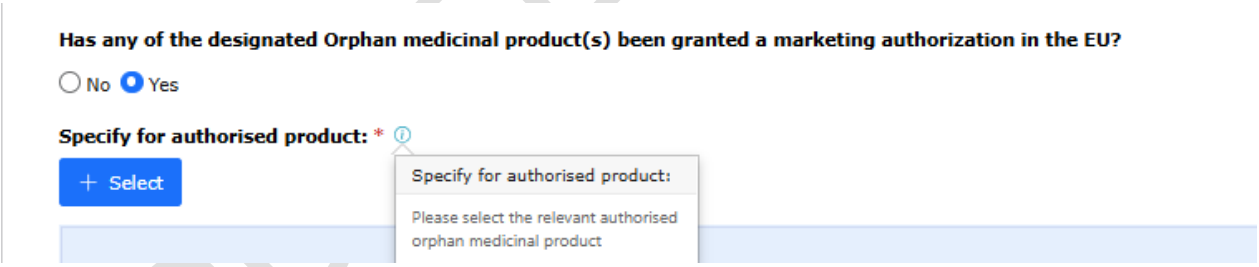
Figure 133 - Selection of Procedure

2.6.2. Information relating to orphan market exclusivity

1. To launch the window to search and select the procedure, click the select button
2. This will launch a lookup window where additional filtering/search criteria can be used to find the relevant procedure
3. The rest of the fields are filled in automatically based on the information held in the database for the selected procedure



2.6.3. Has any of the designated Orphan Medicinal Products been granted a marketing authorisation in the EU



2.6.. Type IB and Type II Variations – Paediatric Requirements

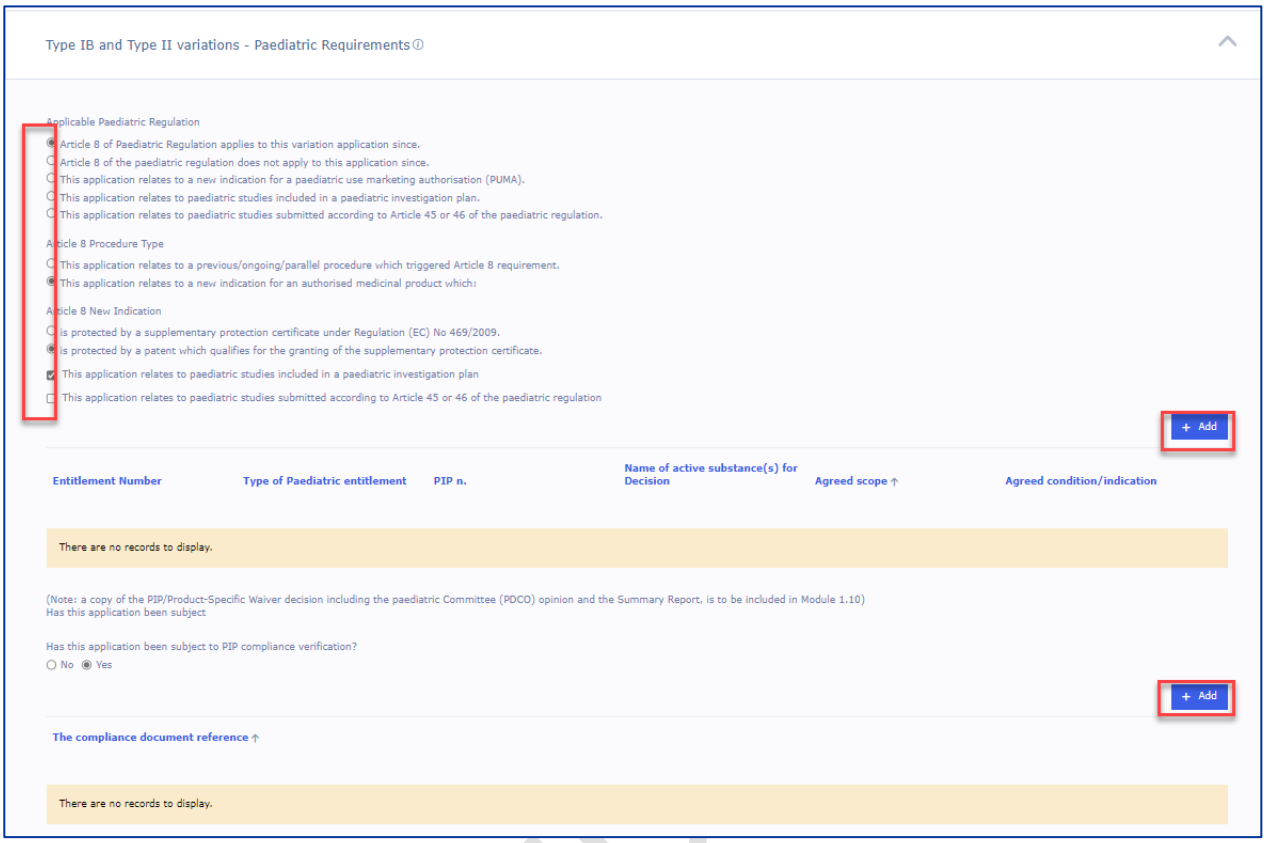


Figure 134 - Type IB and Type II Variations – Paediatric Requirements

1. Select the Paediatric Entitlement(s) using the search

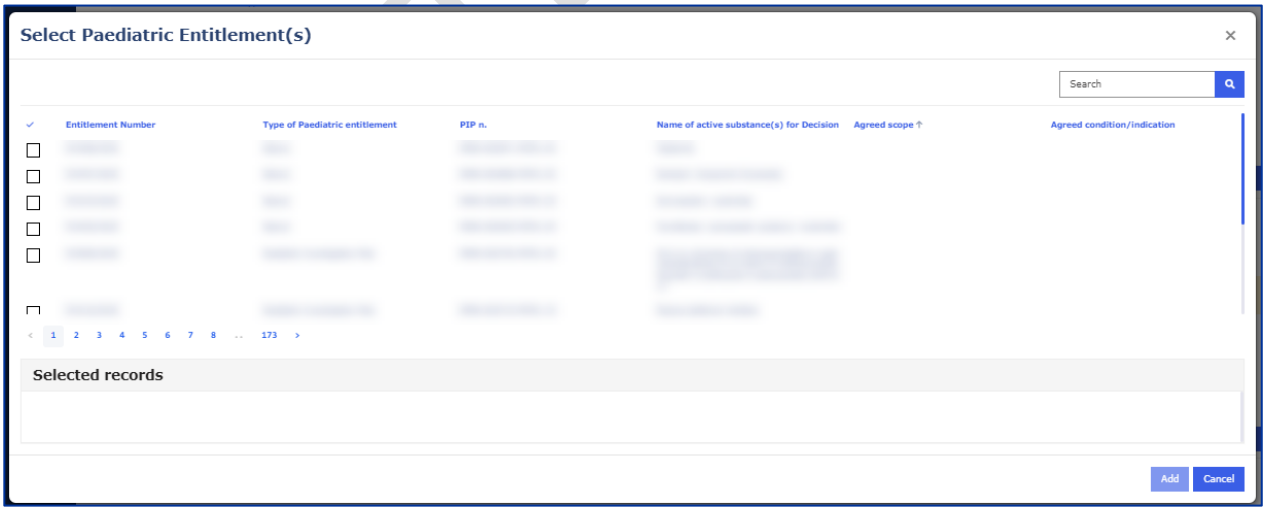


Figure 135 - Selection of Paediatric Entitlement(s)

2. Add the entitlement

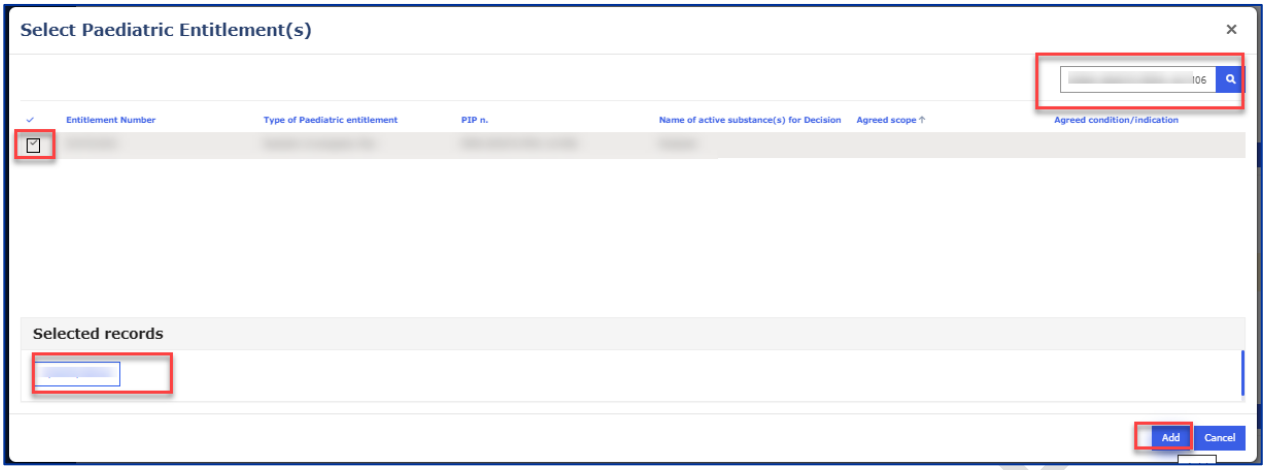


Figure 136 - Addition of Paediatric Entitlement(s)

The details are shown in the table and the entitlement can be removed using the arrow on the right

Figure 137 - Recap Table of Paediatric Entitlement(s)

3. Add information relating to PIP compliance, this is done by clicking the Add button and entering the Procedure number in the free text field;

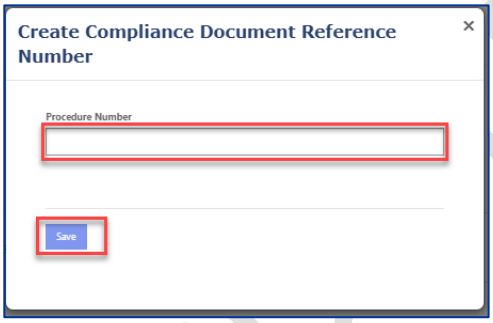


Figure 138 - Creation of Compliance Document Reference Number

2.6.4. Type II Variations – Extended data exclusivity / market protection

Figure 139 - Type II Variations – Extended data exclusivity/market protection

2.7. Finalisation section

The 'Finalisation' section contains the sections Annexed Documents, Declaration of the Applicant, Proof of Payment and Signature. Refer to the Finalisation step on the left-hand side of the menu. This section has been divided in 4 sub sections. You can expand the sections by clicking anywhere in each of the subsection fields (accordion).

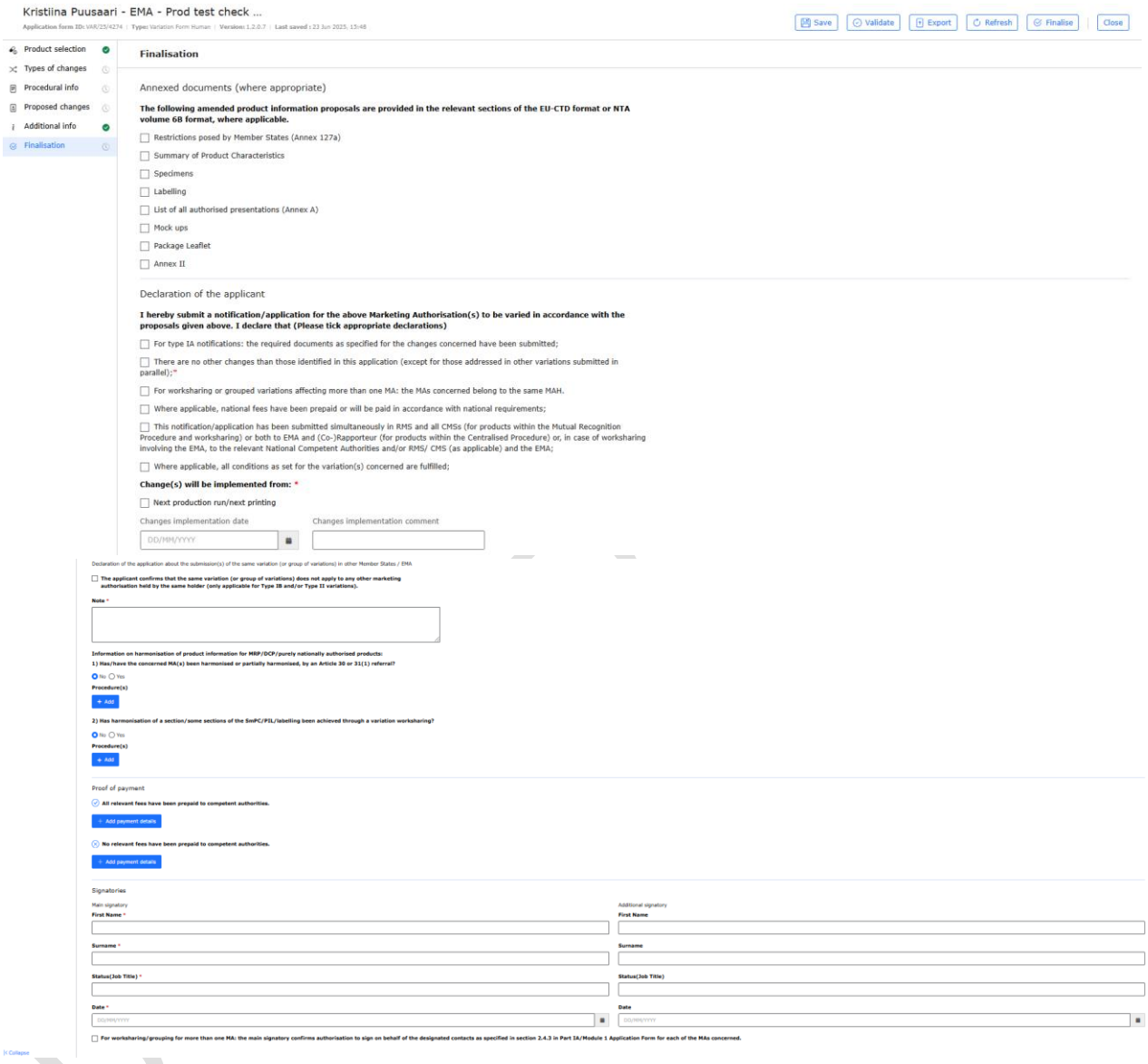


Figure 140 - Finalisation Process

2.7.1. Annexed documents (where appropriate)

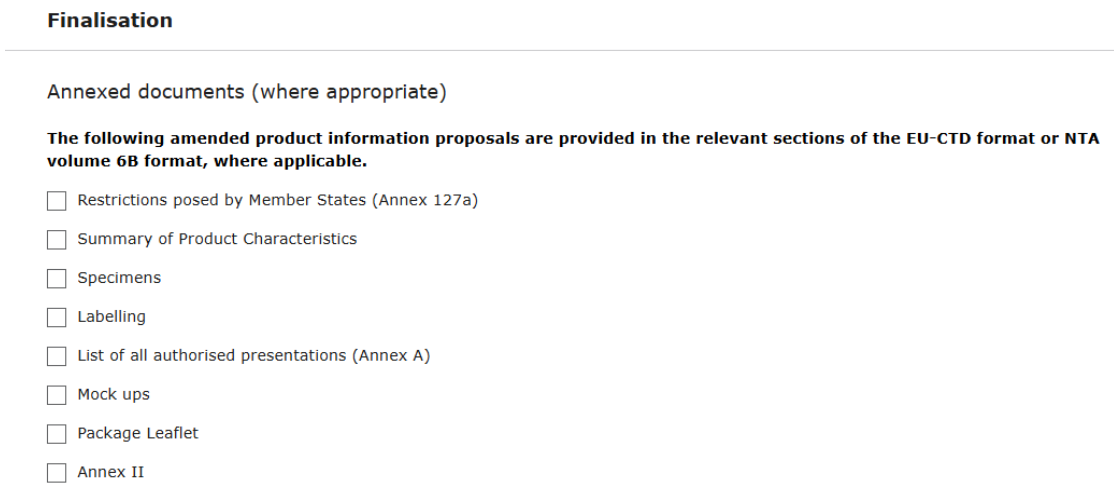


Figure 141 - Annexed Documents

2.7.2. Declaration of the applicant

The Declaration of the applicant section has number of declarations, some only visible, for variations that contain CAPs and impact the product information. The implementation date field is visible only for Type IB and/or Type II variations.

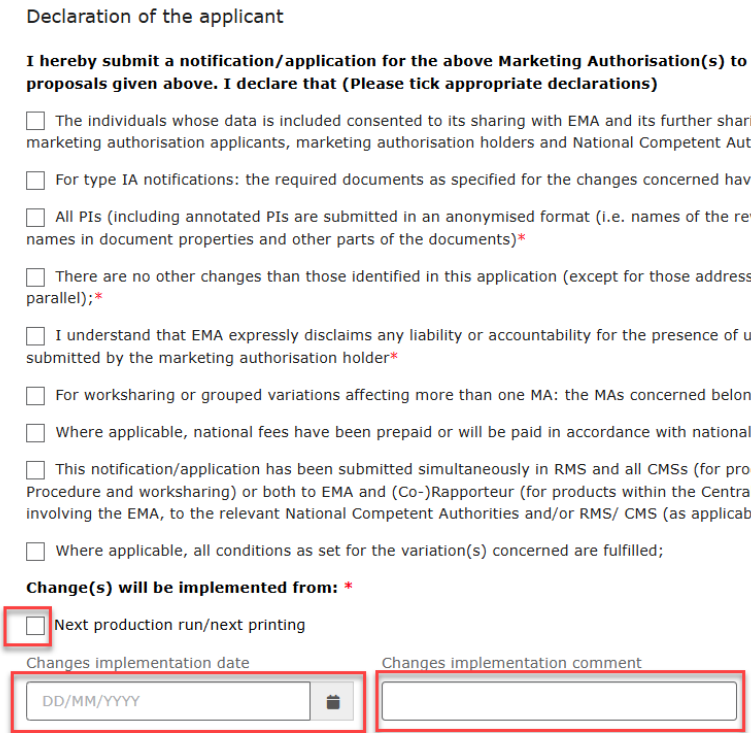


Figure 142 - Declaration of the Applicant

2.7.3 Declaration of the application about the submission(s) of the same variation (or group of variations) in other Member States / EMA

In the Declaration of the applicant confirms that the same variation (or group of variations) does not apply to any other MA held by the same holder. This is a new Mandatory field applicable for all Type IB and Type II variations.

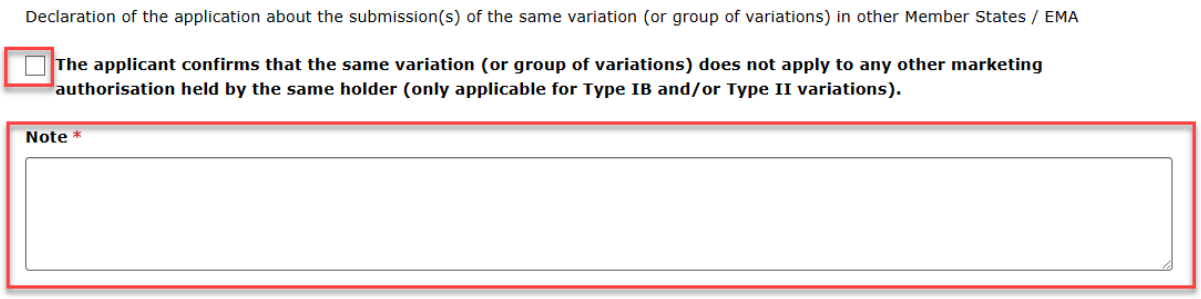


Figure 143 - Declaration of the Applicant

2.7.4 Proof of Payment

For Centralised Procedure applications the Proof of Payment section is defaulted to 'No', however, for Type II variations the MAH details are listed in the Proof of Payment section. If you do not wish to display the Proof of Payment section for variations containing CAPs, you will need to remove the section by clicking the trashcan icon.

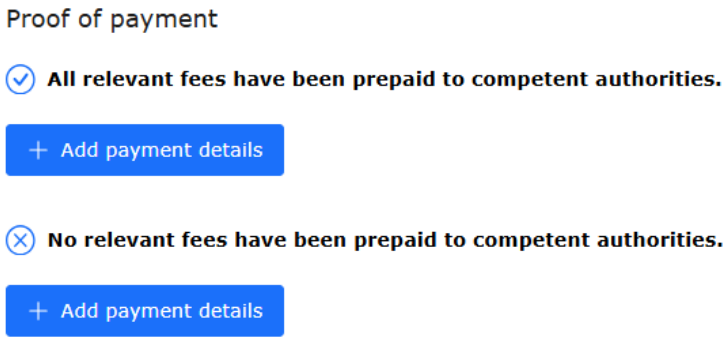


Figure 144 - Proof of Payment

2.7.5 . Signatories

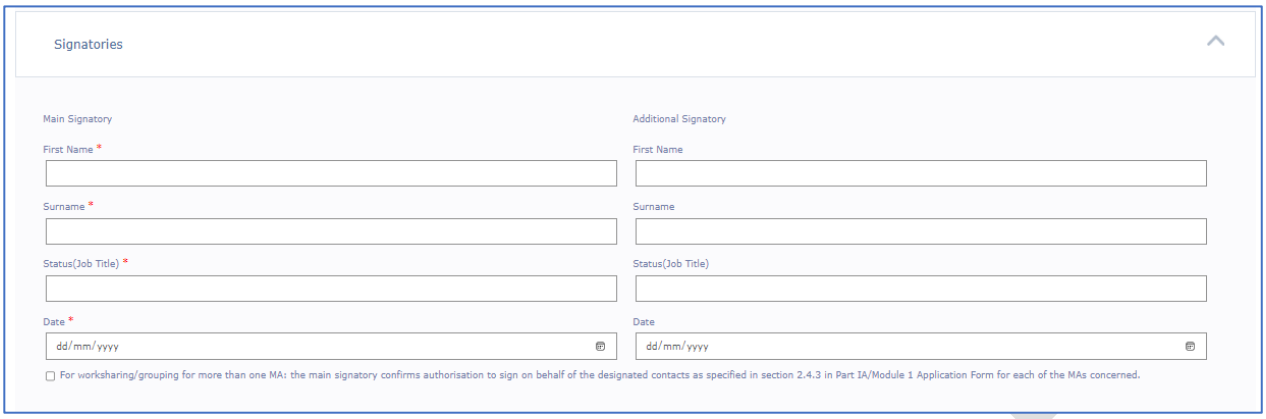


Figure 145 - Signatories

The signatories' section is comparable to the one in the interactive pdf with the exception that currently it is only possible to add 1 additional signature. New change request has been raised to allow additional signatories to be added.

The pdf eAF exported from the web user interface cannot be edited outside the PLM Portal. The forms cannot be signed in the web user interface.

If the user wishes **to include a signature in exported pdf**, this can be done using external digital signature tool, however, the use of simple Adobe signature without a certificate (e-Sign) or an image of a signature can no longer be used in conjunction with the 'integrity stamp' feature. Adobe signature with a certificate or any other digital signature tool should work, although some issues have been identified by some users. In case of any issues, please do contact your signature tool provider and additionally, please contact EMA to report the issue.

2.7.6 . Finalisation of the form – Integrity stamp (warranty)

Once the form editing has been finalised the form should be finalised and exported to be included in the eCTD sequence.

There is a difference between simply 'exporting' the form and 'finalising' the form. The export can be done at any time and as many times as required during the editing process. The 'finalisation' of the form is normally done only once, when the form is ready to be submitted and no further changes are needed. Using the 'Finalise' feature moves the form from the 'drafts' tab to the 'completed' tab in the list of applications view. Once the form has been finalised, it is no longer possible to edit the form.

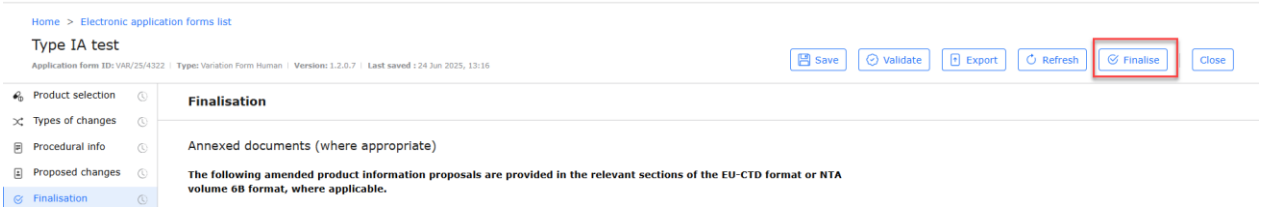


Figure 146 - Finalise Submission

The date printed in the integrity stamp is simply the time and date when the form was exported from the PLM Portal. It is **not** the date when the form was submitted. To ensure that you meet the submission deadline, please create the form and prepare your eCTD submission package in advance of the submission deadline.

1. Click the 'Finalise' button to trigger final, full form validation and the export of the form with the 'Integrity stamp'.

3. Exporting the form content to a PDF

3.2. PDF Export

The form content can be exported as a pdf at any time. During the development and test a message is displayed to explain that validation errors were found. For now you can ignore this message and always respond Yes.

You can see the progress of the export in the moving bar that is constantly updated while the export is being prepared

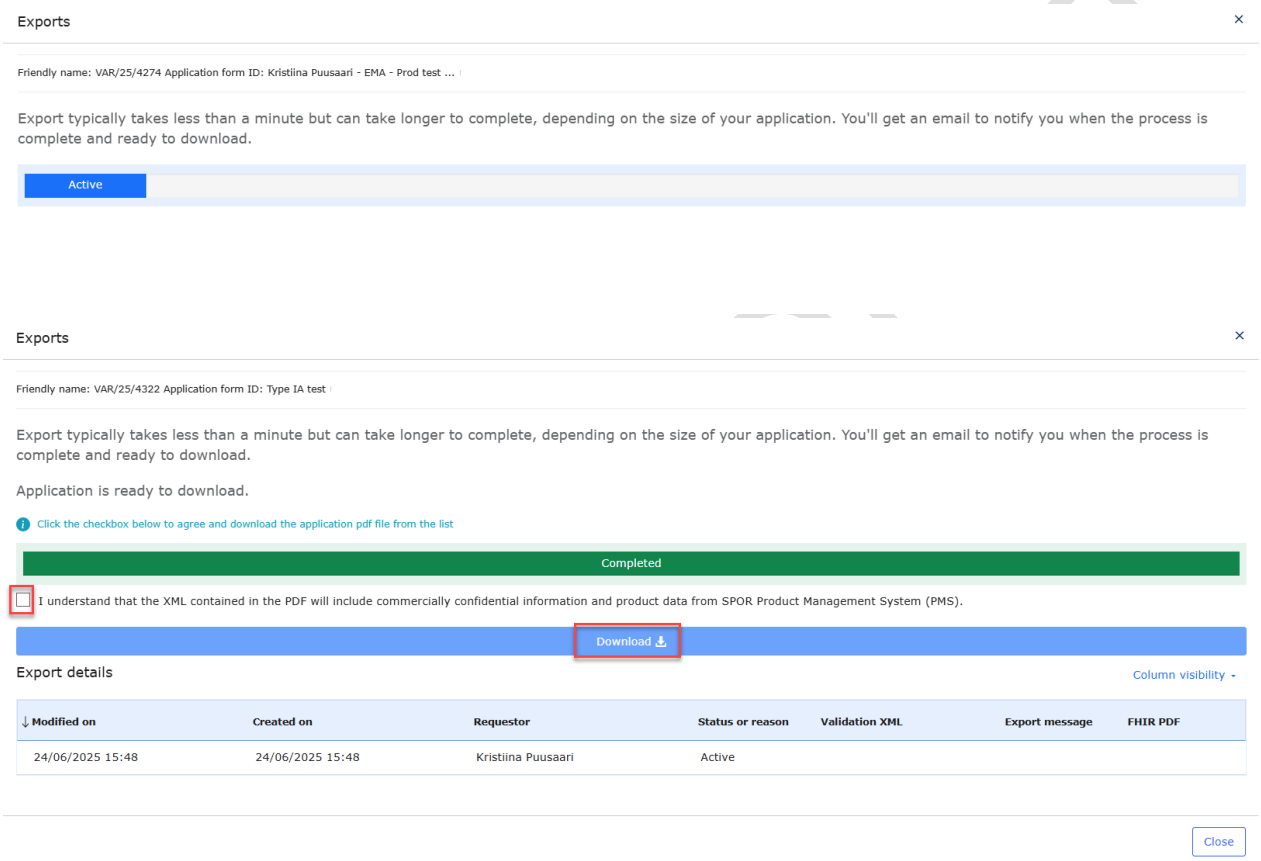


Figure 147 - Preparation of Export

Once the status is shown as Completed, you will get a blue bar across the screen showing 'Download'. When you click this the form will be downloaded to your pc's download folder

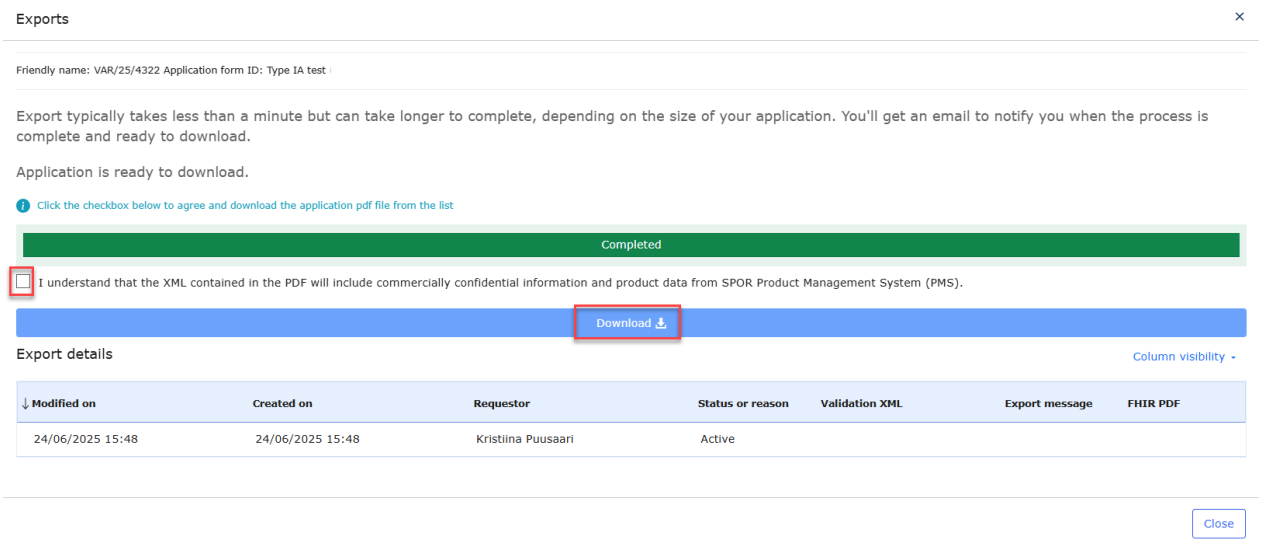


Figure 148 - Export Completed

The downloaded forms normally have a name that consists of letters and numbers. You can save this pdf rendition to be reviewed, signed (more details on the use of digital signatures will be provided) and to be included in the dossier. The pdf can be renamed to reflect the eCTD requirements.

The form contains the FHIR xml which can be used to upload the form content and product information into the receiving regulators systems. Please note that the FHIR attachment and the pdf content must not be edited after exporting. If any changes are needed, please return to the web user interface and make the changes in the web form and export the form again.

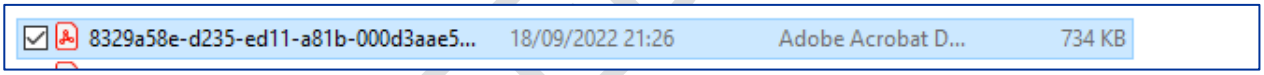


Figure 149 - Exported Form

The form closely resembles the pdf application form. There are some minor differences to the previous version.

The form can be navigated using the left-hand navigation bar or the table of contents as previously.

The FHIR xml can be found under the paper clip, and it can be opened and viewed if needed. This is mainly meant to be machine read to feed information to receiving systems.

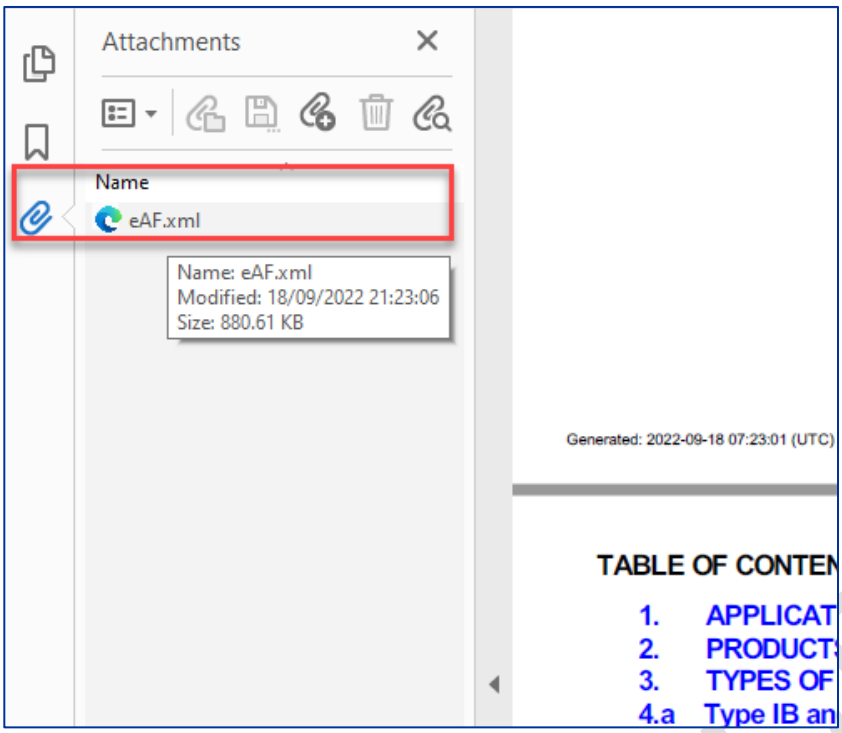


Figure 150 - FHIR xml

This XML file does not appear to have any style information associated with it. The document tree is shown below.


```
▼<Bundle xmlns="http://hl7.org/fhir">
   <id value="c683504d-41fa-4cf6-9de5-0fb249f77eaa"/>
  ▼<meta>
     <versionId value="V0.1"/>
   </meta>
   <type value="collection"/>
  ▼<entry>
   ▼<resource>
    ▼<Task>
       <id value="8329a58e3aae59e6f8d69a30ce653a8a"/>
     ▼<contained>
      ▼<List>
         <id value="taskProductList"/>
         <status value="current"/>
         <mode value="working"/>
        ▼<entry>
         ▼<item>
            <reference value="MedicinalProductDefinition/3de609f13aaa0711f8d69a30ce653a8a"/>
          </item>
        </entry>
       </List>
     </contained>
     ▼<contained>
      ▼<Task>
         <id value="variation-06abee533aaa0cebf8d69a30ce653a8a"/>
        ▼<identifier>
           <system value="http://ema.europa.eu/fhir/scopeIdentifier"/>
           <value value="C.I.6.a - Variation Type II - 1"/>
         </identifier>
        ▼<partOf>
           <reference value="#"/>
         </partOf>
         <status value="requested"/>
         <intent value="order"/>
        ▼<code>
         ▼<coding>
            <system value="https://spor.ema.europa.eu/v1/lists/100000152091"/>
            <code value="100000152602"/>
            <display value="C.I.6.a Addition of a new therapeutic indication or modification of an approved one"/>
          </coding>
          <text value="100000152602"/>
         </code>
        ▼<input>
         ▼<type>
          ▼<coding>
             <system value="https://spor.ema.europa.eu/v1/lists/9000000001"/>
             <code value="9000000004"/>
             <display value="Not Applicable"/>
           </coding>
         </type>
         <valueBoolean value="false"/>
        </input>
```


Figure 151 - XML file - Document Tree

3.3. PDF Requirements

There are no specific Adobe version requirements with regards to opening of the pdf rendition. As opposed to the interactive pdf eAFs, the pdfs generated from the web user interface cannot be edited by the users and therefore they can be simply opened with any pdf reader.

4. Support

4.1. The PLM Portal eAF Guidance materials

The updated PLM Portal home page contains links to various different guidance documents, videos and Q&A documents. You can follow the quick link to eAF guidance page from the eAF tile or you can access the main PLM Portal Guidance and Support page from the link in the blue bar at the bottom of the page. From the Guidance and Support page you can find links to all related systems and guidance materials.

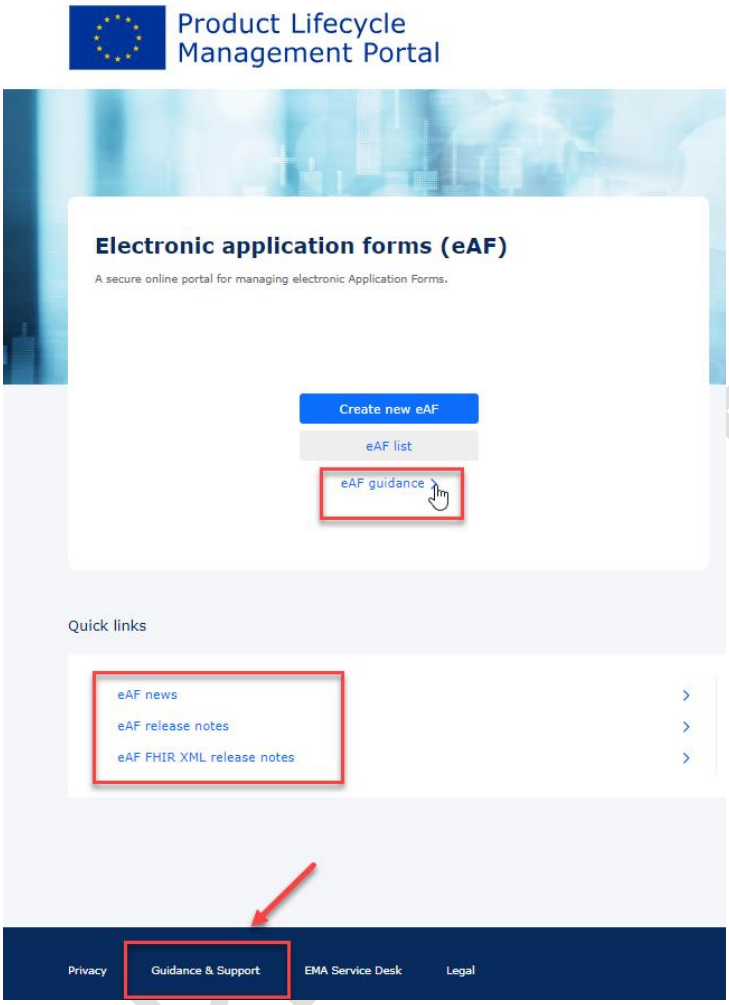


Figure 152 - eAF PLM Portal

4.2. The PLM Forum

The **PLM Forum** is a public platform where users (primarily applicants) can stay up to date on the latest PLM news (e.g., new PLM features, release information, known issues), ask each other questions, provide suggestions, and discuss best practices. While posts are visible to everyone, users need to be logged in to the portal to create a new thread or reply to an existing one.

EMA staff may intervene in the forums, but replies to individual questions cannot be guaranteed, as the forum does not replace the established EMA communication channels:

1. EMA Service Desk for questions on the use of the portal and for reporting faults;
2. EMA Account Management for access and registration requests;

3. Ask EMA for general questions not related to a specific submission/procedure;

Direct replies to eAF emails (without changing the subject), when responding to issues relating to a specific procedure.

Please note any text contained in the threads of the forum is publicly available, therefore please do not post any type of confidential information.

4.3. The Service Desk

For **technical support** with the PLM Portal, please use directly the PLM Portal-eAF section of the EMA Service Desk portal. This includes issues related to creation of new accounts, access to existing accounts, uploading data and performance of databases.

If you have a user account for a system hosted by EMA, you should use the same username and password for this service. Otherwise, please Sign up for a new account or reset your login credentials.

The Service Desk portal is optimised for use with Chrome, Edge, Firefox or Safari web browsers. If you encounter problems, please use one of these browsers instead.

Report an issue with the PLM Portal - eAF, to create a ticket for the issue you are experiencing, or,
Request information about the PLM Portal - eAF, to create a ticket for the question you have.

Depending on the issue or question, you can select from different problem areas:

- PLM portal – eAF FHIR XML (issues and questions on the FHIR xml)
- PLM portal – eAF General (topics covering multiple aspects and/or general nature)
- PLM portal – eAF PDF export (issues/discrepancies/errors in the generated pdf)
- PLM portal – eAF Web-form User Interface (issues/questions/improvements relating to the web UI)

Please provide a clear description of the issue and provide screenshots or the generated pdf as attachment as these can help to solve the query a lot faster.

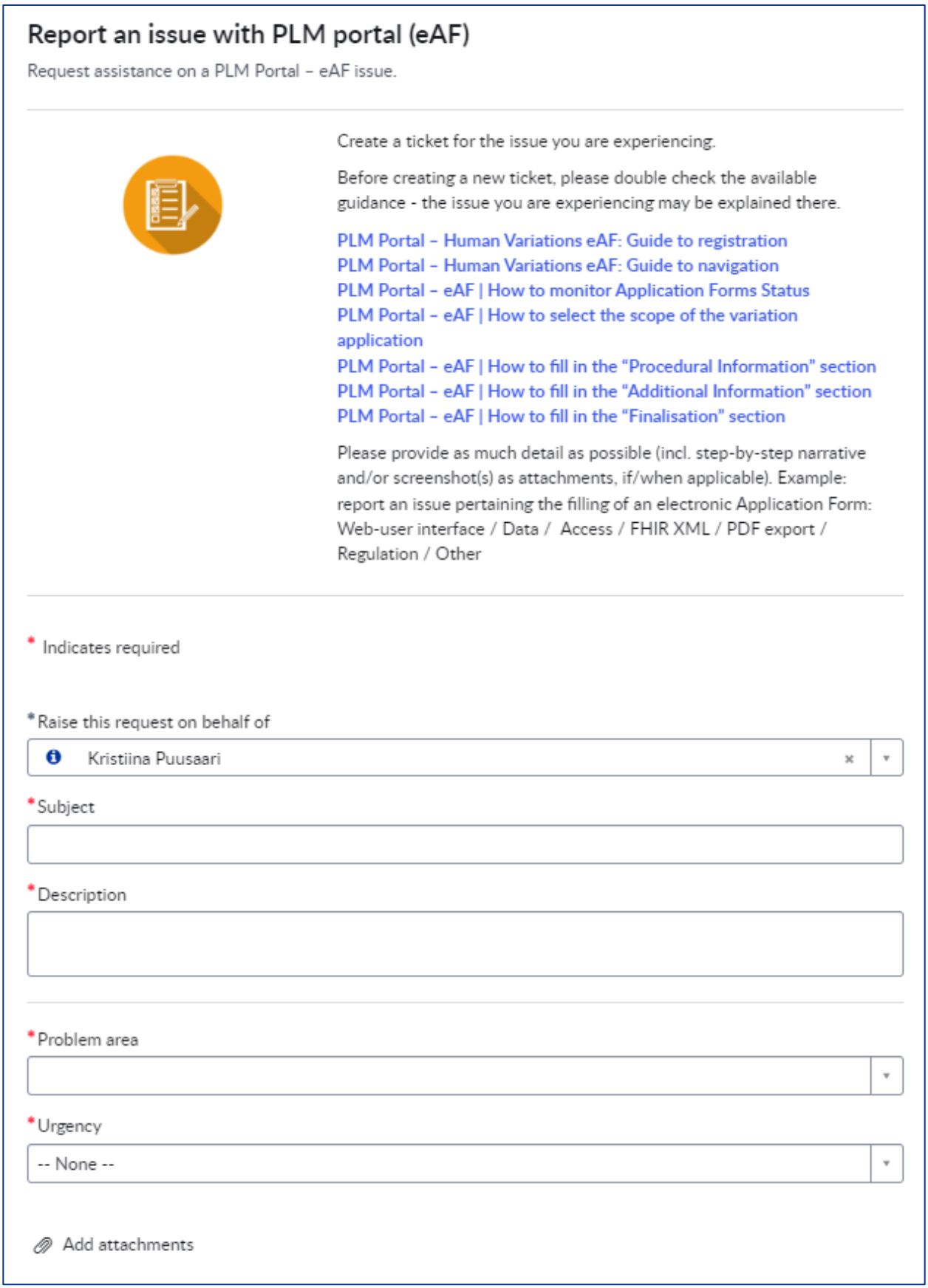


Figure 153 - Report an Issue with PLM Portal (eAF) Form

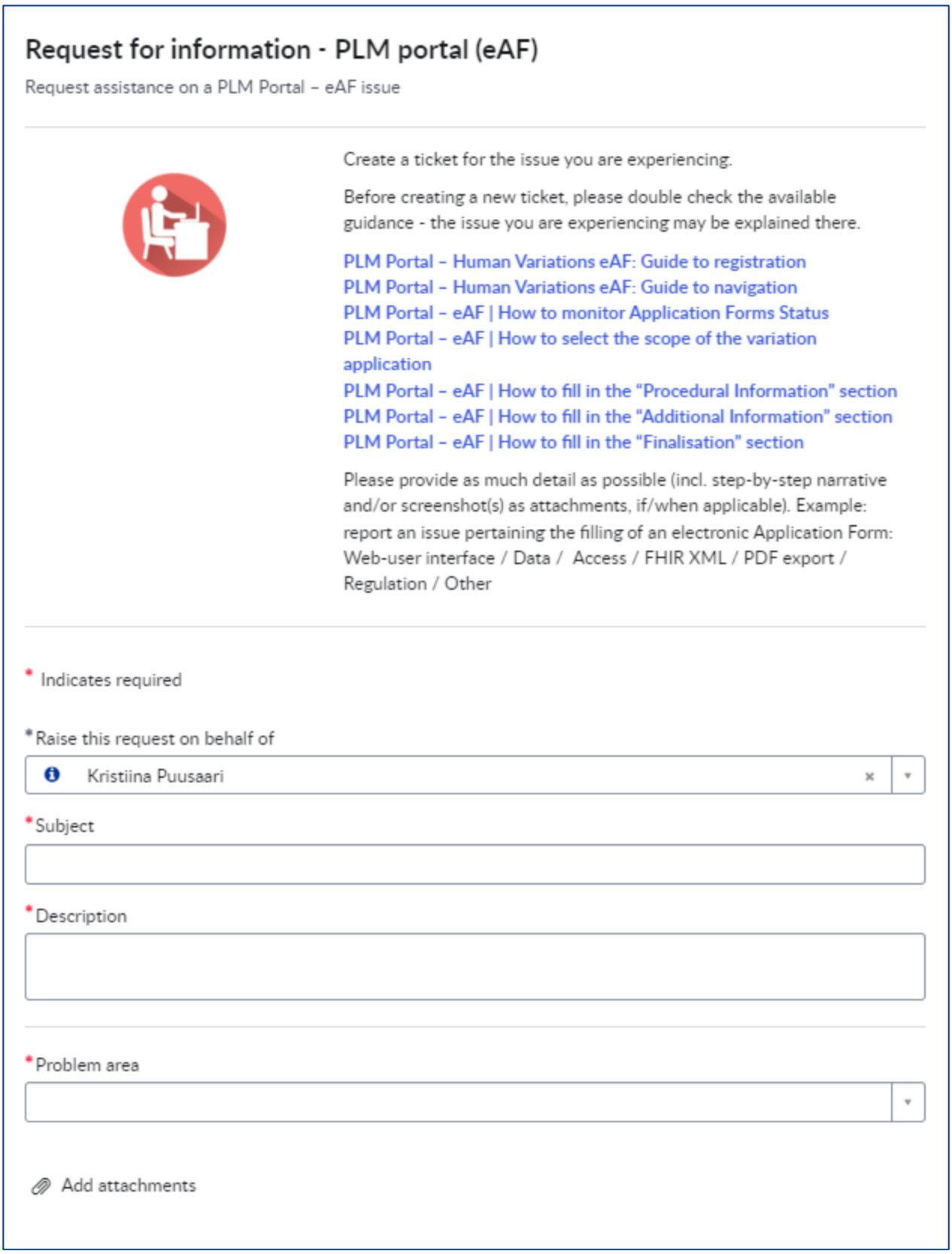


Figure 154 - Request for Information - PLM Portal (eAF) Form

Important note: please select the correct category when reporting issues through the EMA Servicenow. It is important that Data issues and/or SPOR issues are not reported under eAF to ensure that they will be addressed timely.

Please see more details on how to report issues from this presentation slides 22-24.

4.4. The PLM Chatbot

The **PLM Chatbot** is an artificial intelligence tool where users are offered with digital assistance for commonly asked questions in an interactive mode. You are encouraged to use the buttons to navigate through the information or to type your question directly into the chat.

To access and engage with the PLM Chatbot, click on the icon, available on the right-hand side of the PLM Portal.

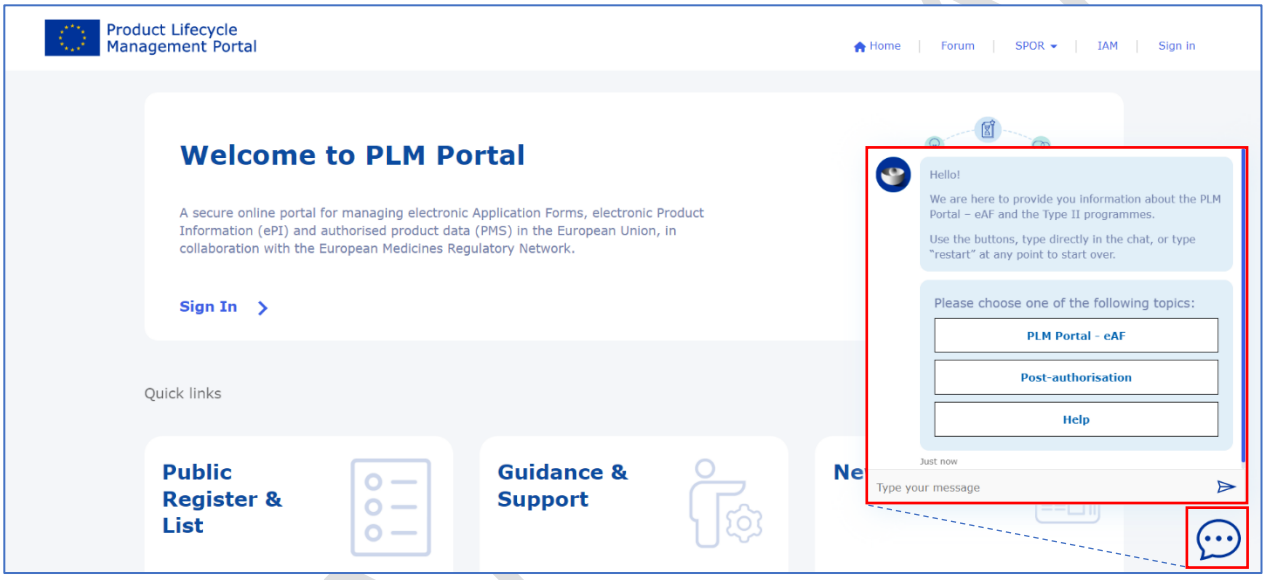


Figure 155 - PLM Chatbot