EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Product Lifecycle Management Portal – Human Variations eAF

Guide to navigation - Updated

Version 1.3

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EUROPEAN MEDICINES AGENCY
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Acronym key and glossary terms

EMA European Medicines Agency

PLM Product Lifecycle Management

eAF Electronic Application Form

SPOR Management Services for Substances, Products, Organisations and Referentials

OMS Organisation Management Service (part of SPOR)

IT Information Technology

FAQ Frequently Asked Questions

MAH Market Authorisation Holder

ATC Anatomical Therapeutic Chemical code

PSMF Pharmacovigilance System Master File

1. Purpose and Context

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/

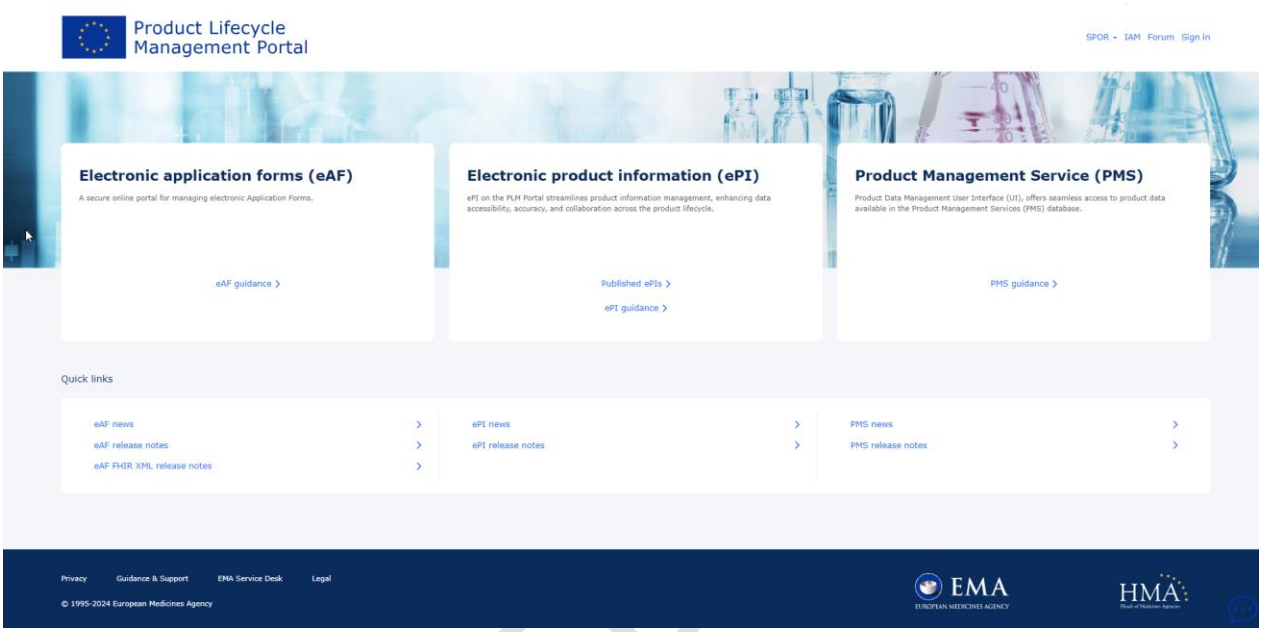


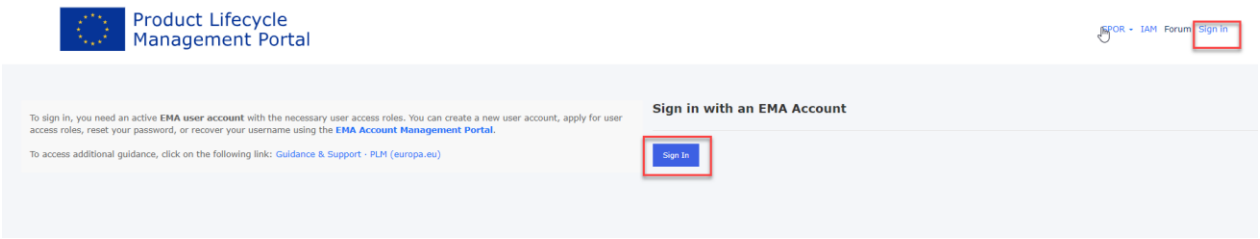
Figure 1 - Sign-in

2.1.2. How to create a new electronic Application Form

Users with an active EMA account and either with the eAF Applicant Manager or the eAF Applicant Coordinator role if they originate from the pharmaceutical industry or 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.



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,

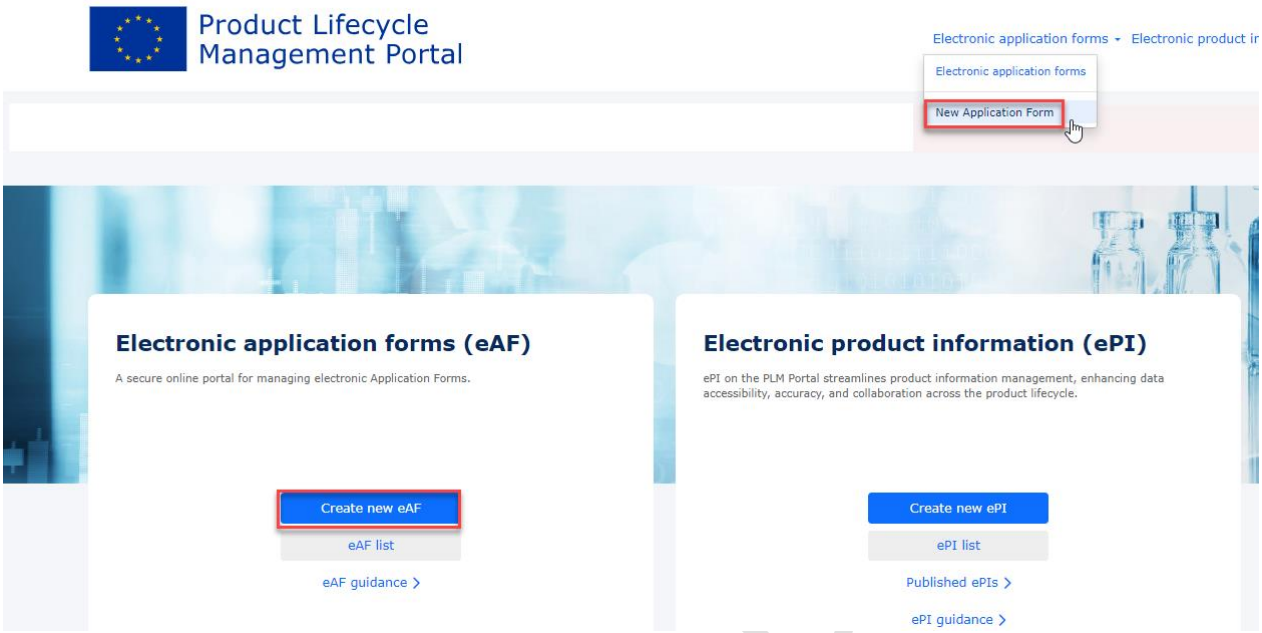


Figure 2 – New Application Form

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.

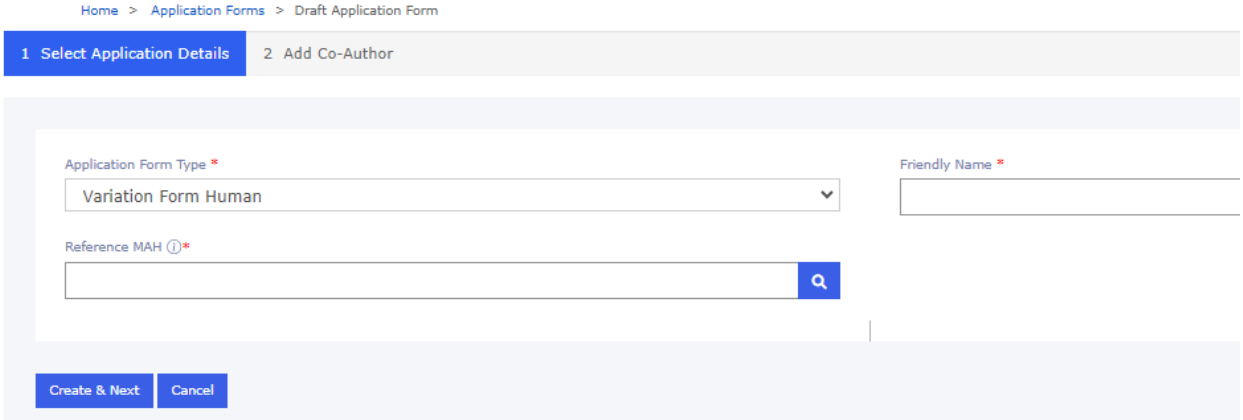


Figure 3 - Application Form Type

- Add a **Friendly Name** (e.g.: *WonderPill Type II quality*) – ideally this name should be **meaningful** and 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. Try and make it meaningful so that you can find your variation form again if needed.
- Please note that it is now possible to change originally given Friendly name.
    - To change or update the Friendly name, please select the option '**Rename application form**' from the application list right had menu

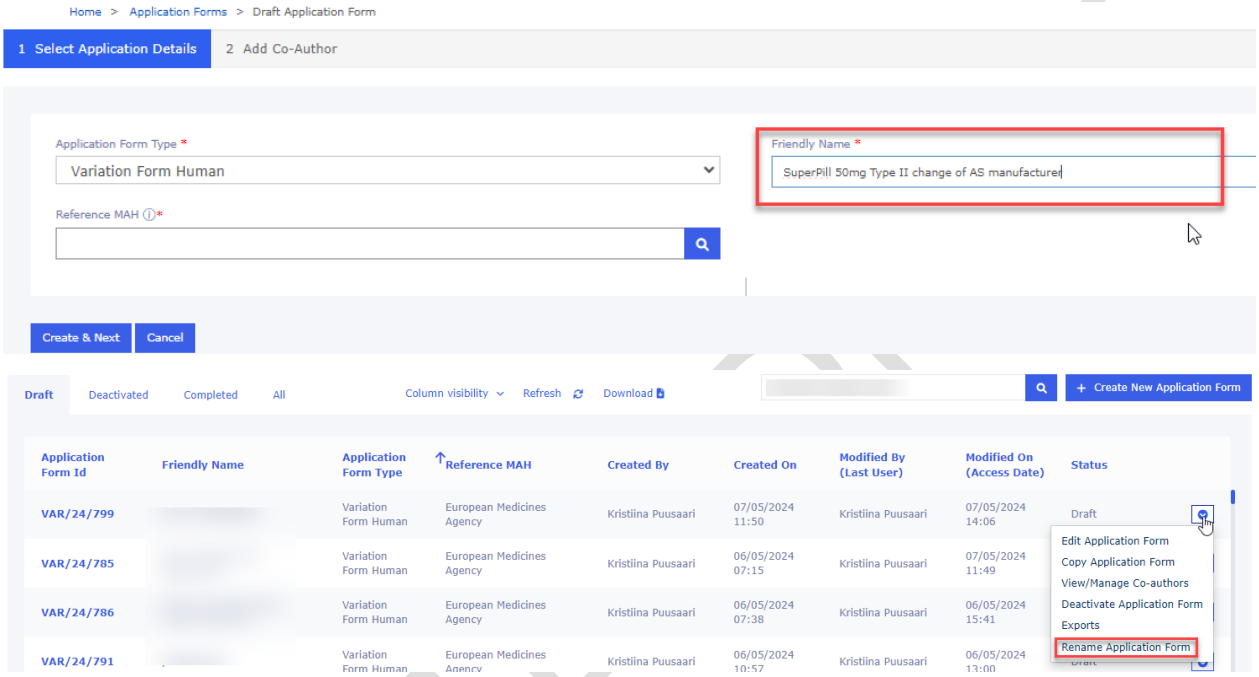


Figure 4 - Application Details

- Add a **Reference MAH**, by using the icon (e.g.: *UAT-LOC11*) – you can search for the MAH using various different attributes, such as the LOC or ORG-id, the company name or address.

It is currently not possible to search organisations with multiple attributes at the same time, for example company name and the country like it is possible in the interactive pdf. To get a better, more matching result, please type for example a part of the address or search using the LOC or ORG id.

NOTE: *Please pay extra attention when selecting organisations/locations, that the location you select is 'active' in OMS. There is an existing production bug in the system that indicates locations that are 'inactive' in OMS as 'active' in the PLM Portal eAF.*

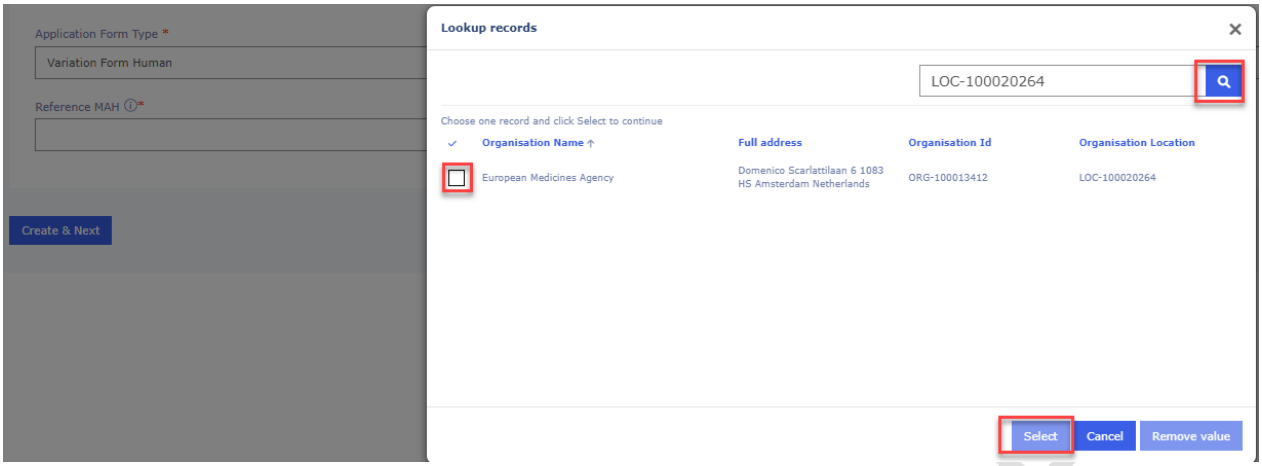


Figure 5 - Reference MAH

- *Click* Select *to select the correct MAH from the search results. 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 perform this search as many times as needed.

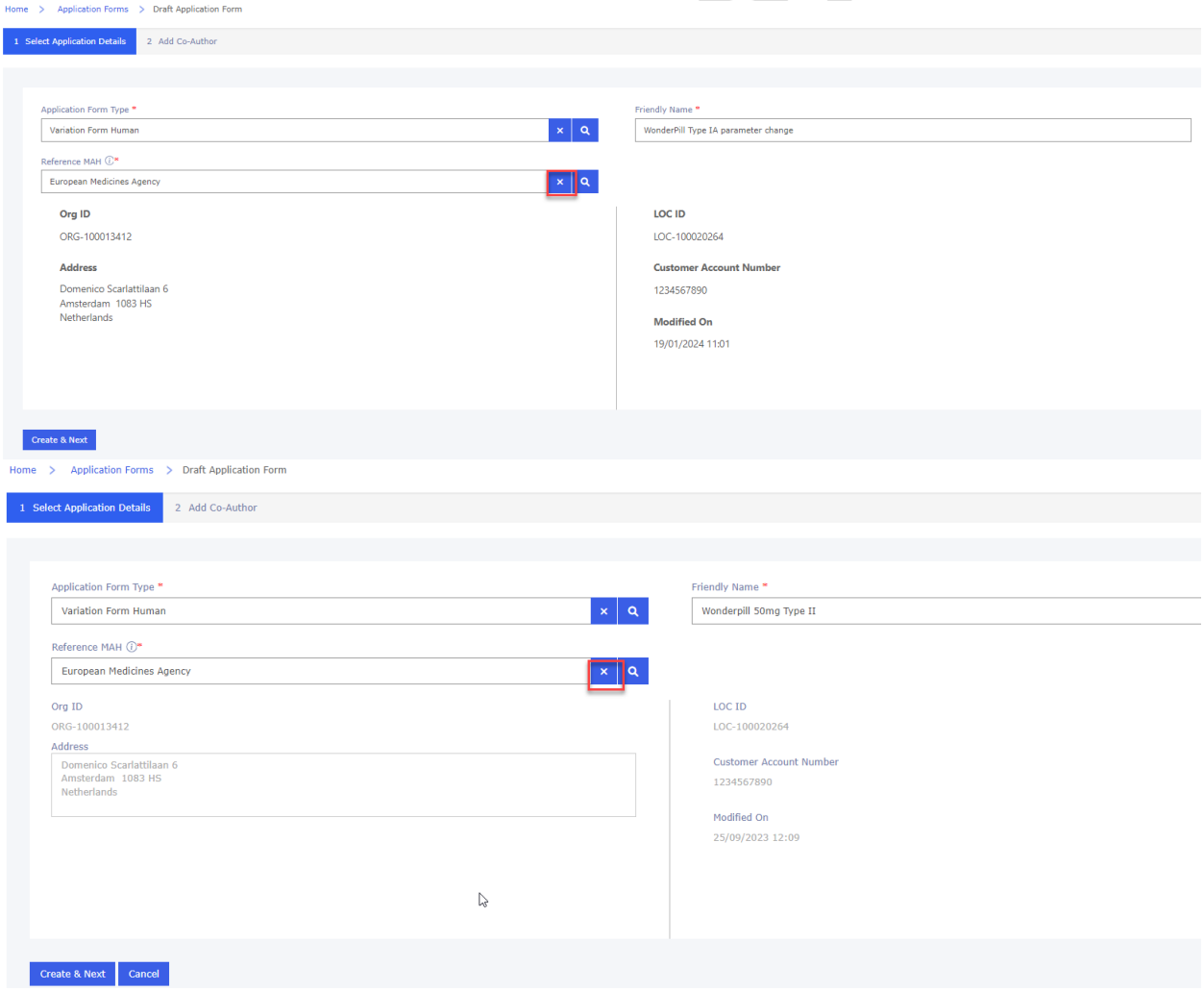


Figure 6 - Create & Next Button

4. Click on the Create & Next button to confirm the selection of the MAH.

   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 MAH and have appropriate eAF user role.

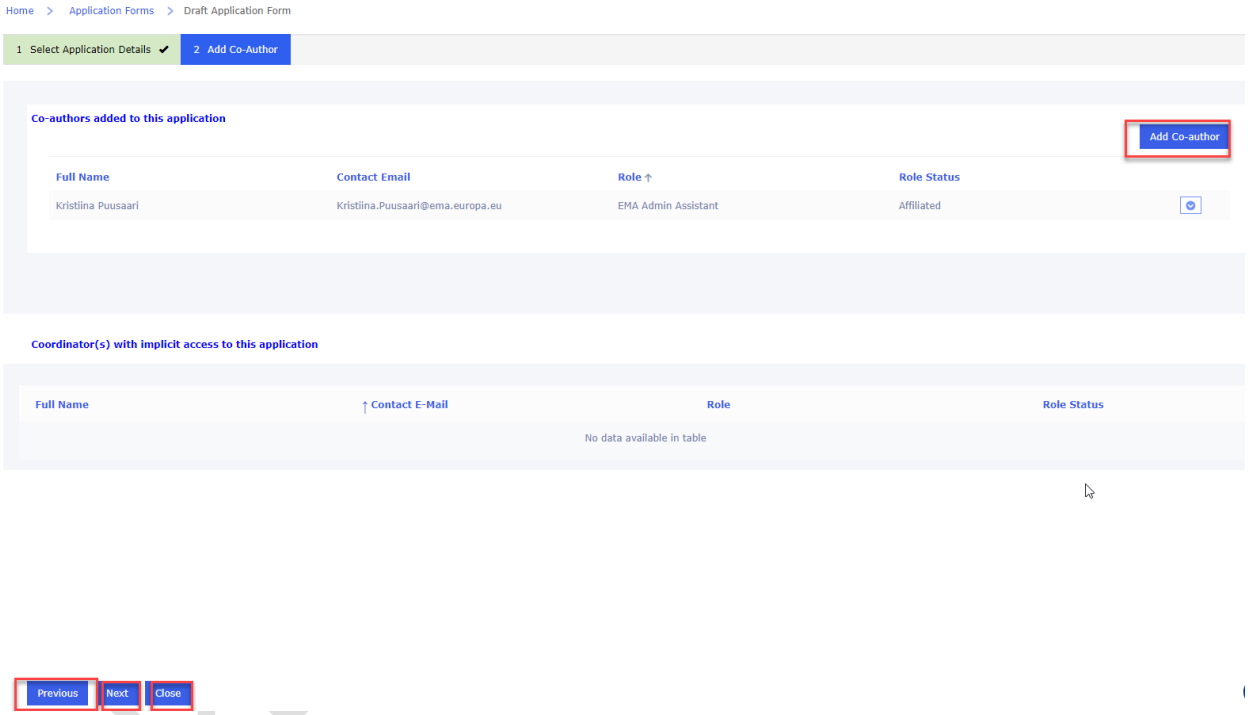


Figure 7 - Add Co-author

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.

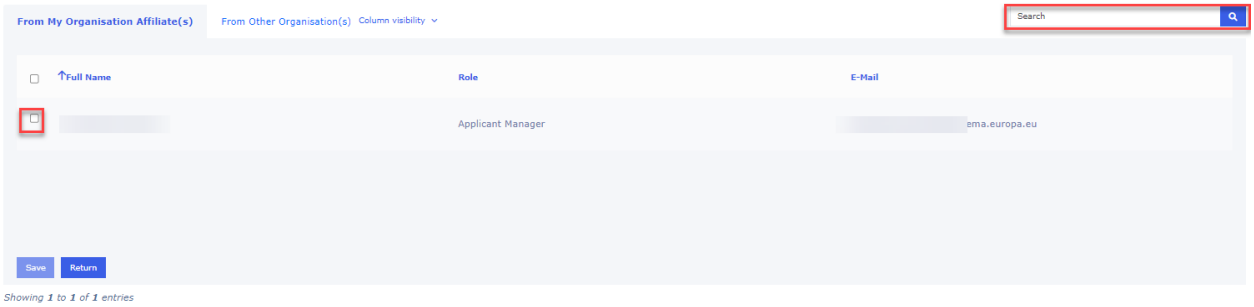


Figure 8 - My Organisation Affiliate(s)' Tab

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.*

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.

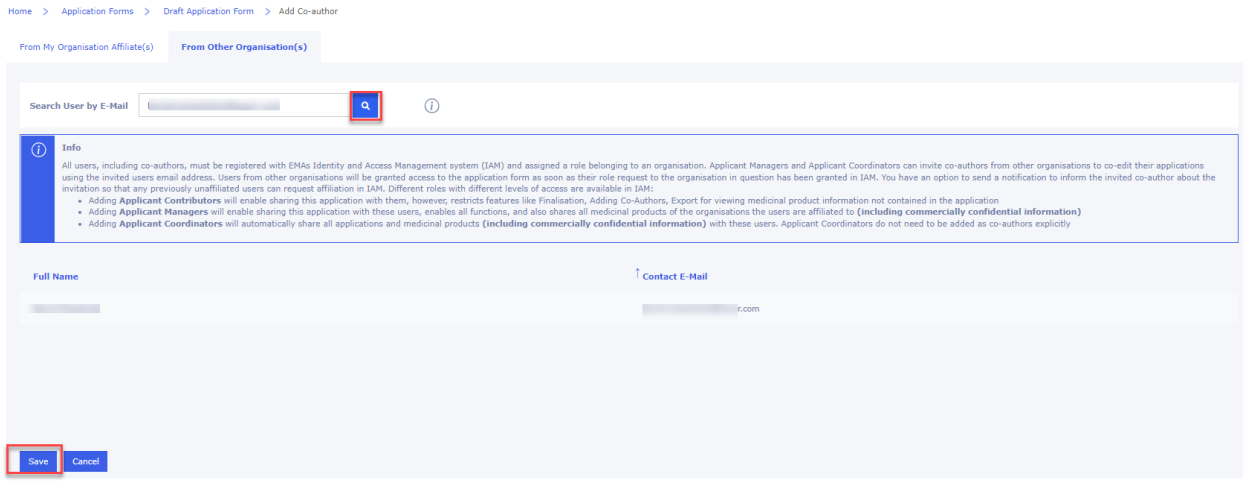


Figure 9 - Add Co-author

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.

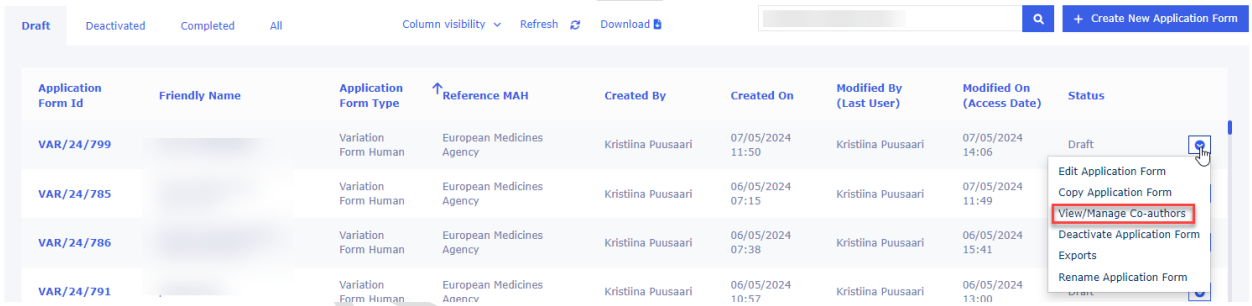


Figure 10 - View/Manage Co-authors

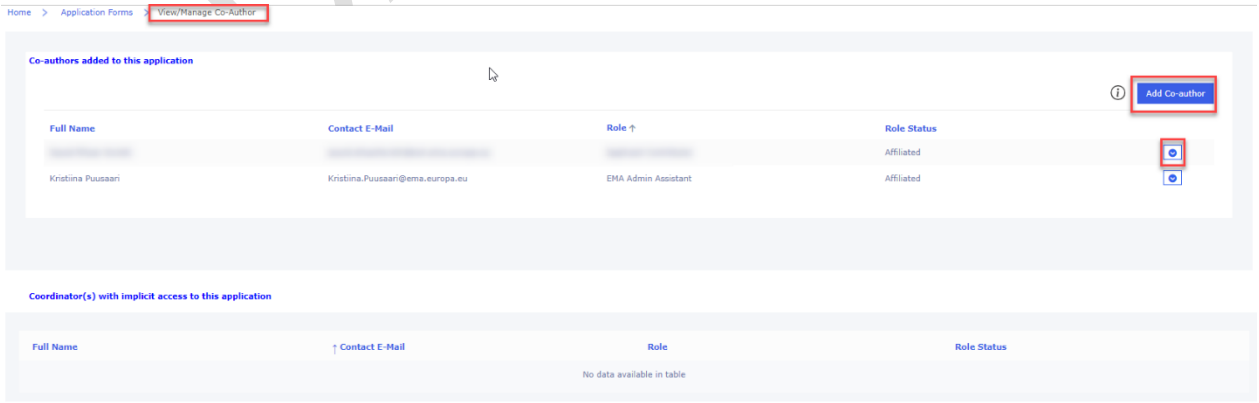


Figure 11 - Add Co-author

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 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. Please note that this feature is not yet available as only CAP products are available in the system.

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

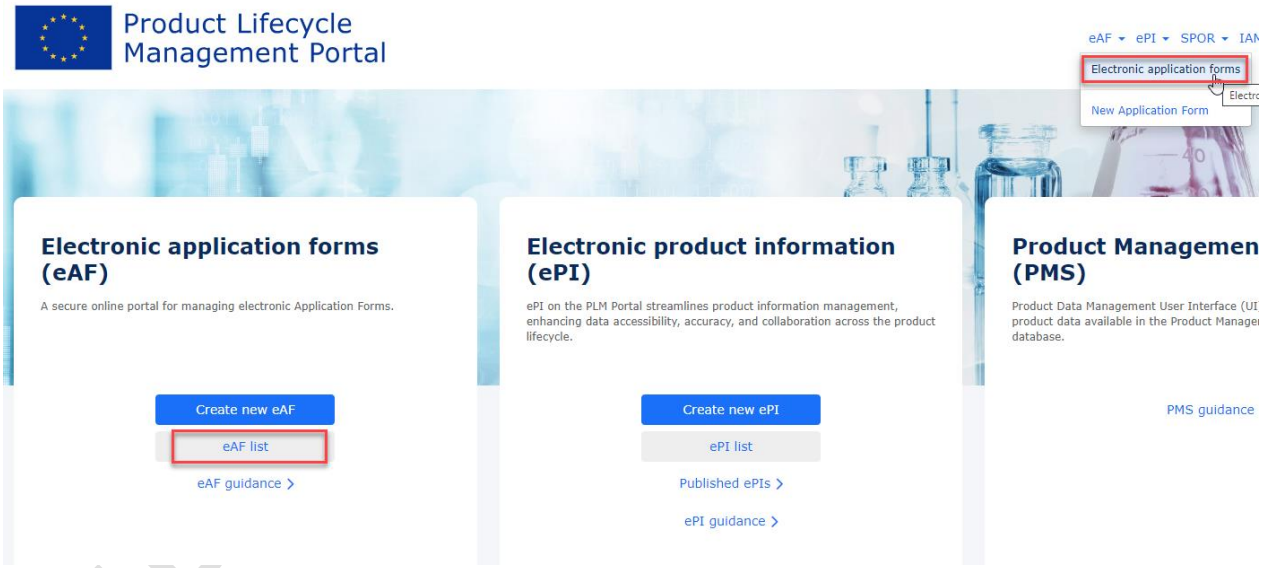


Figure 12 - Application Forms

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.*

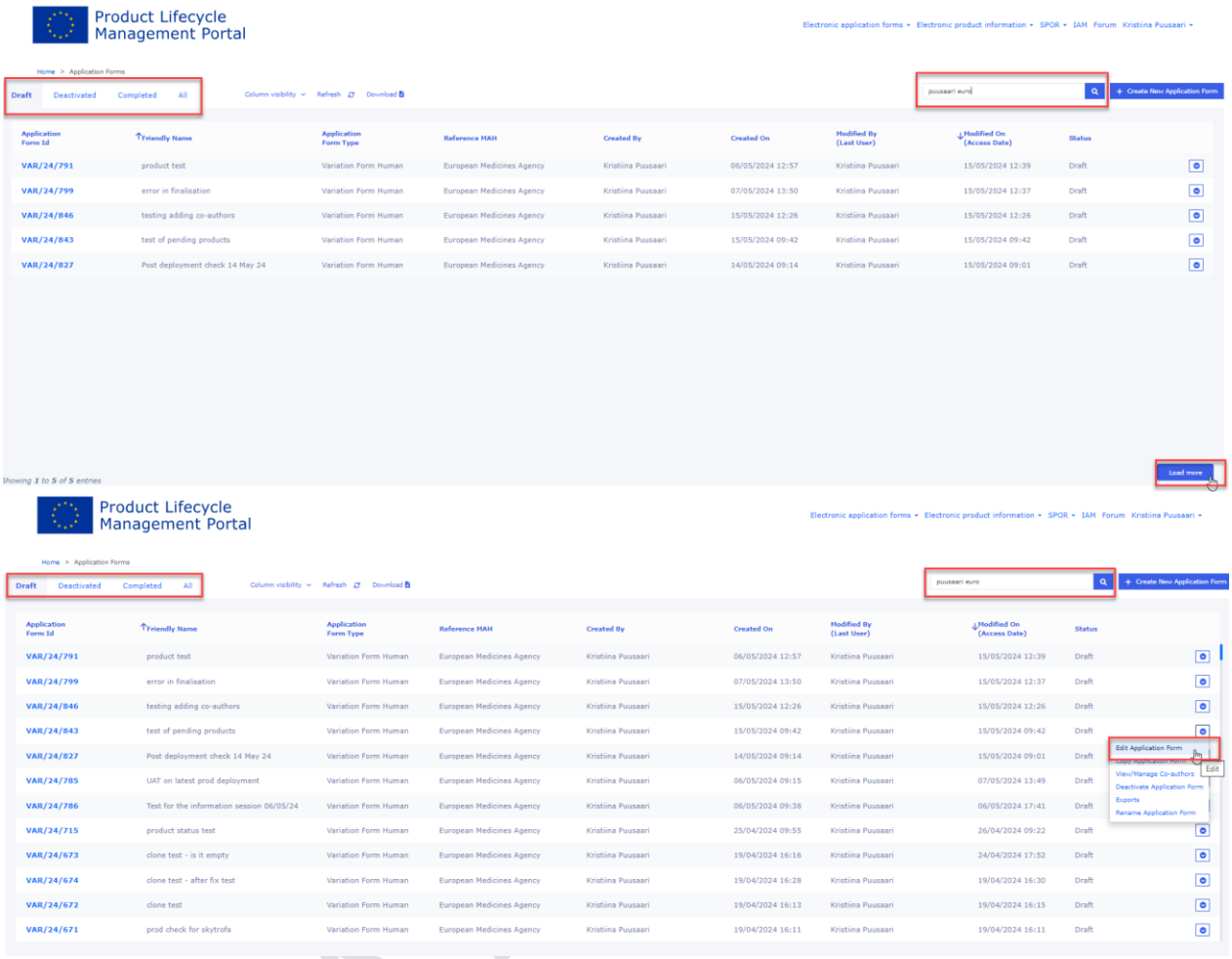


Figure 13 - List of Application Forms

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, 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. In order 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. If you wish not to change the modified by, do not click 'save' anywhere, just cancel to come out of the form.

Click the down arrow 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 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)** (UAT) eAF Applicant Contributor	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	**NCA user(s)** (UAT) eAF Competent Authority User
Draft	- Edit Application Form - View/Manage Co-authors	- Edit Application Form - Exports - Deactivate Application Form - Copy Application Form* - View/Manage Co-authors		
Deactivated	- View Application Form - View Co-authors	- View Application Form - View Co-authors - Exports - Copy 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 - Copy Application Form* - Deactivate Application Form		
All	Operations depend on the Status of the Application Form. Refer to the above operations and statuses			
*	Feature not currently working			

Description of the different operations:

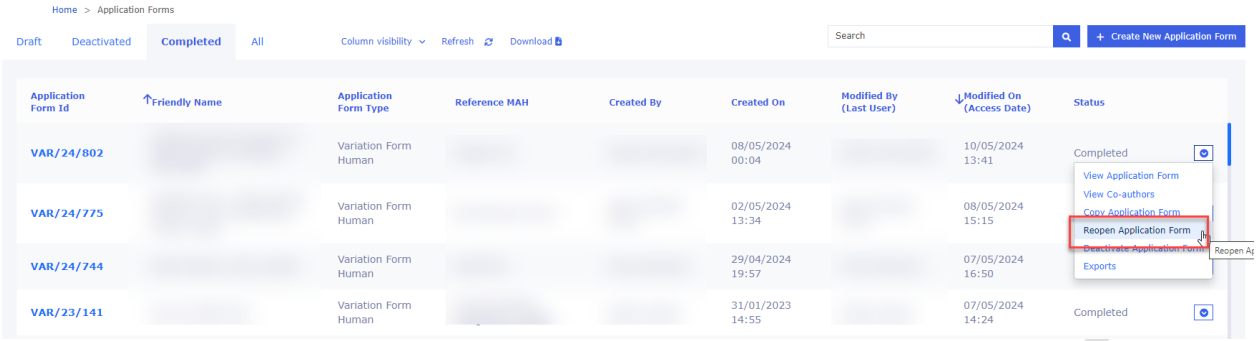
- *Exports – export generates a PDF eAF document which contains an FHIR XML attachment,*
- *View Co-authors (available in the 'Deactivated and Completed tabs) – provides a (read-only) list of all previously added co-authors onto a given Application Form;*
- *View/Manage Co-authors (available in the 'Drafts 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 '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;*
- *Copy Application Form – it creates a separate copy of that Application Form.* ***New****;*
- *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 currently* ***not available*** *.*

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 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'.



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. Copy application (also known as Clone application) function

The copy 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).

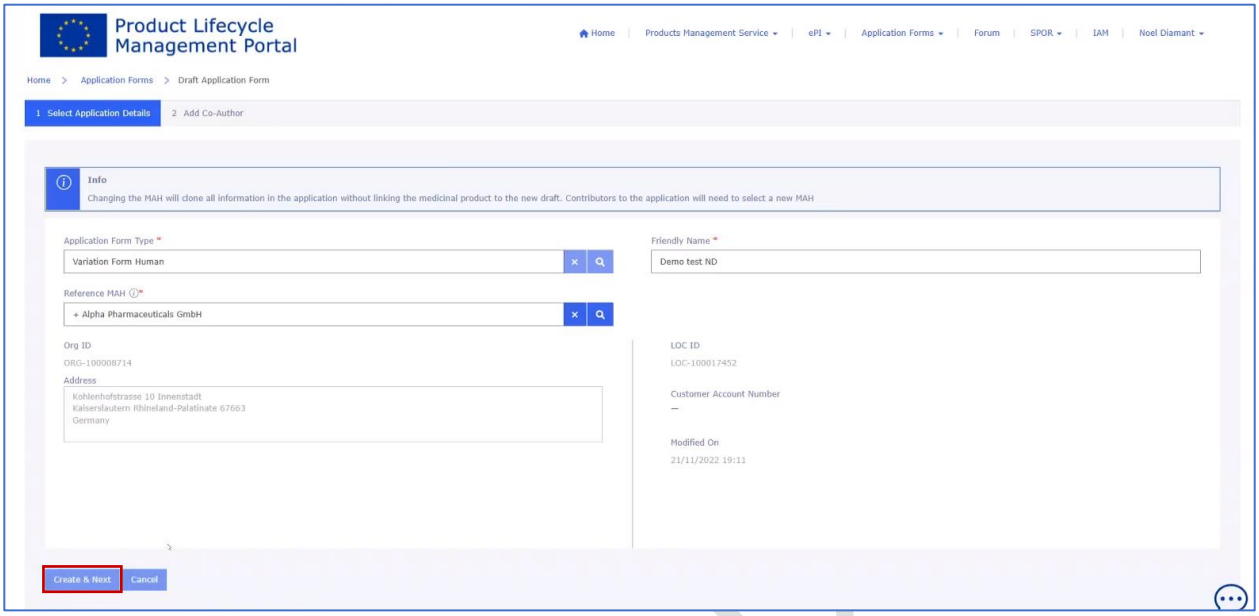
When creating a copy, it is possible to change the MAH. If a different MAH is selected products are removed from the copy to avoid any unintentional sharing of commercially confidential product information.

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.

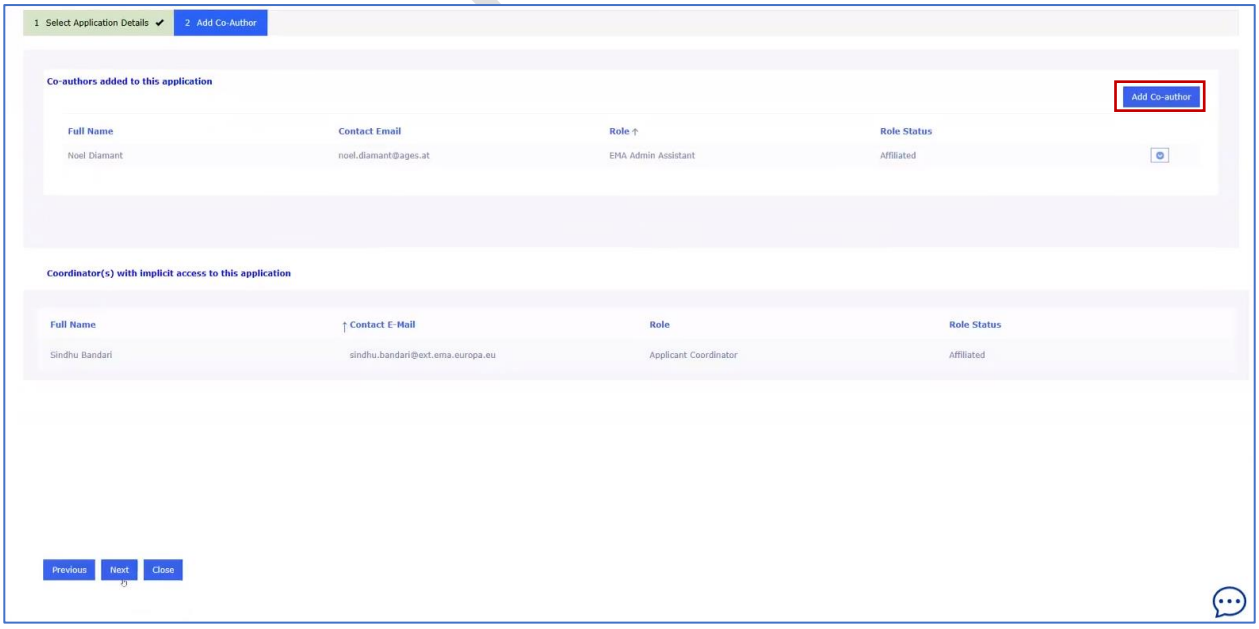
This feature caters to two different scenarios:

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 worksharing variation containing all or some of the same products as in previous application. Occasionally, it

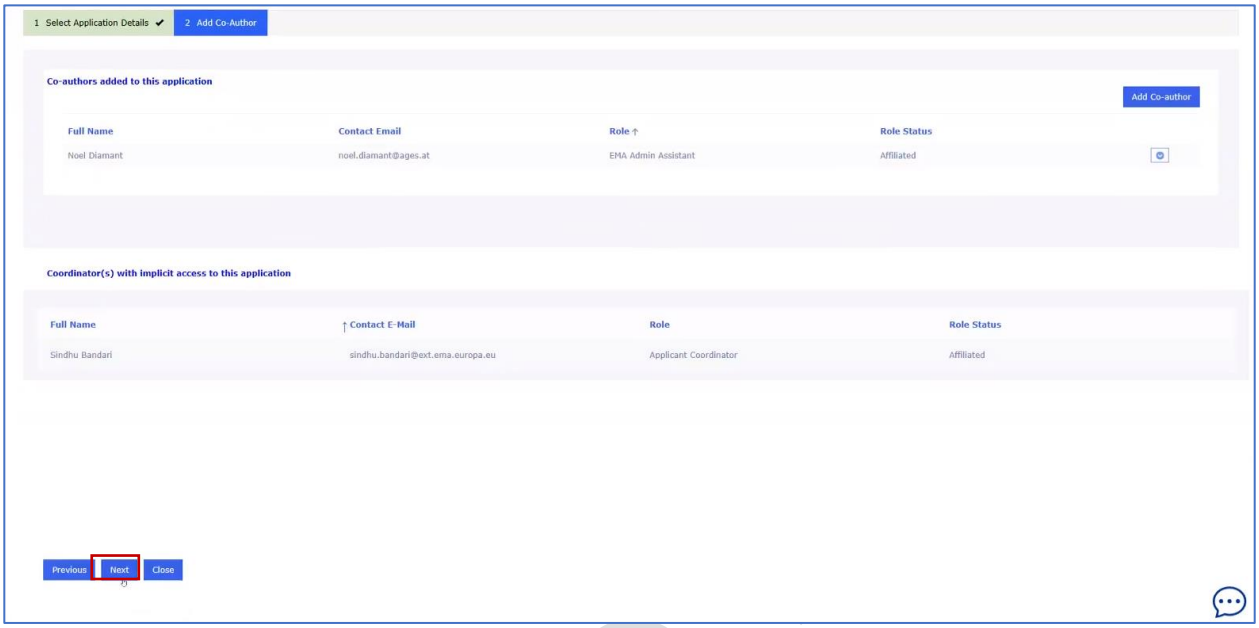
might be necessary to change Marketing Authorisation Holder (MAH) and access limitations might prevent the cloning of products, ensuring adherence to security protocols, and consequently, only other relevant information will be cloned.



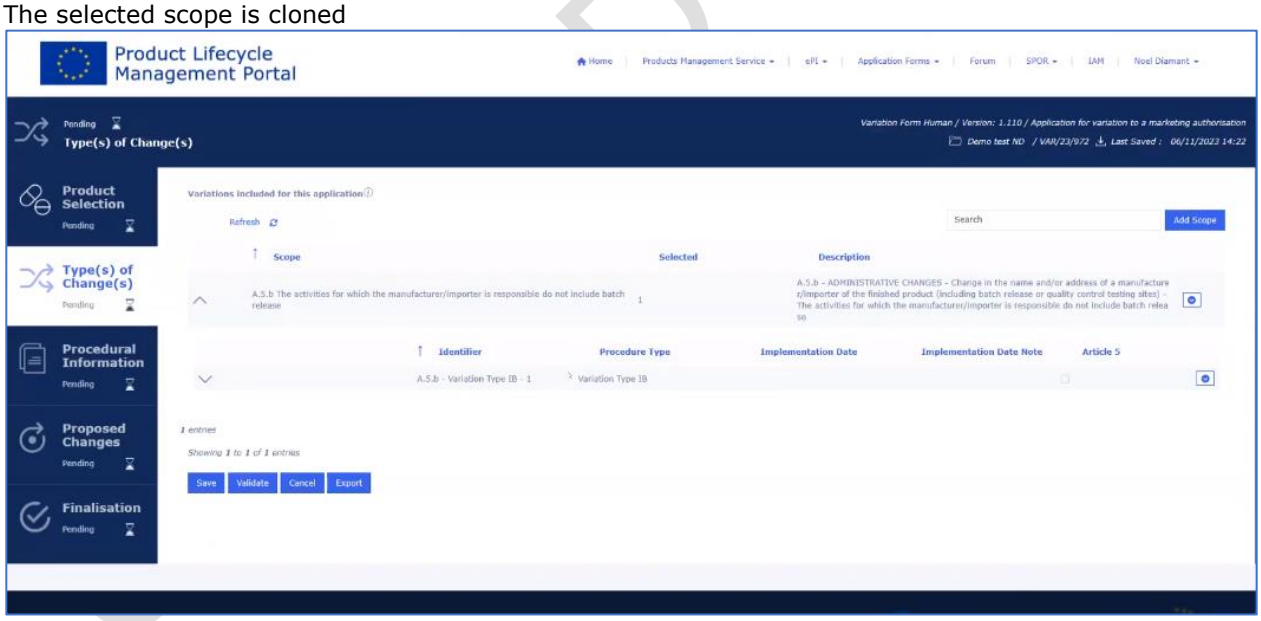
- Upon selecting "Create and Next," the process involves recognising the user initiating the cloning procedure, possessing inherent access to the application. Within the organisation, individuals holding a coordinator role have overarching visibility into all applications, thus eliminating the necessity 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.



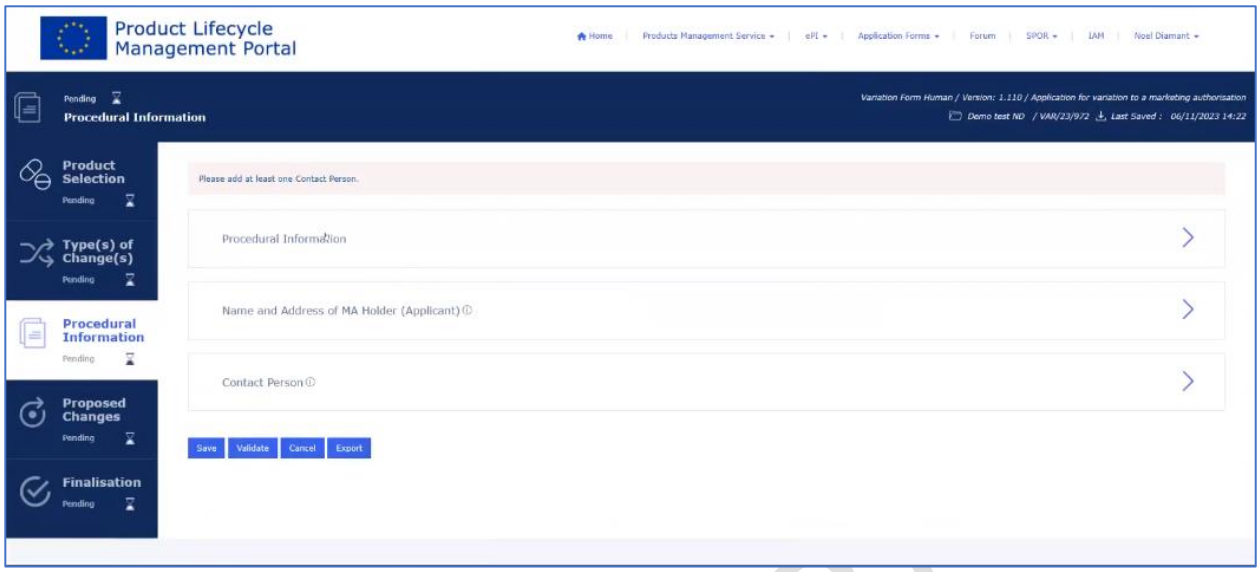
- Upon completion of these setup configurations, click on the "Next" button to start a comprehensive duplication process. This includes replicating all previously entered data—such as products, scopes, and proposed changes—ensuring the transfer of all relevant information to the newly created clone.



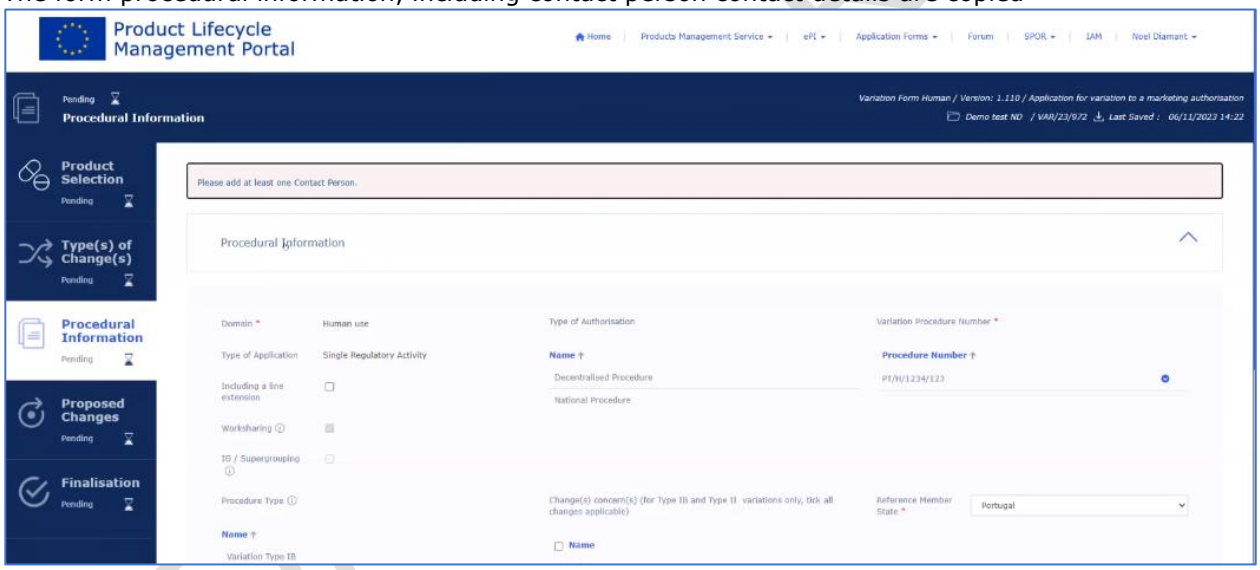
The selected scope is cloned



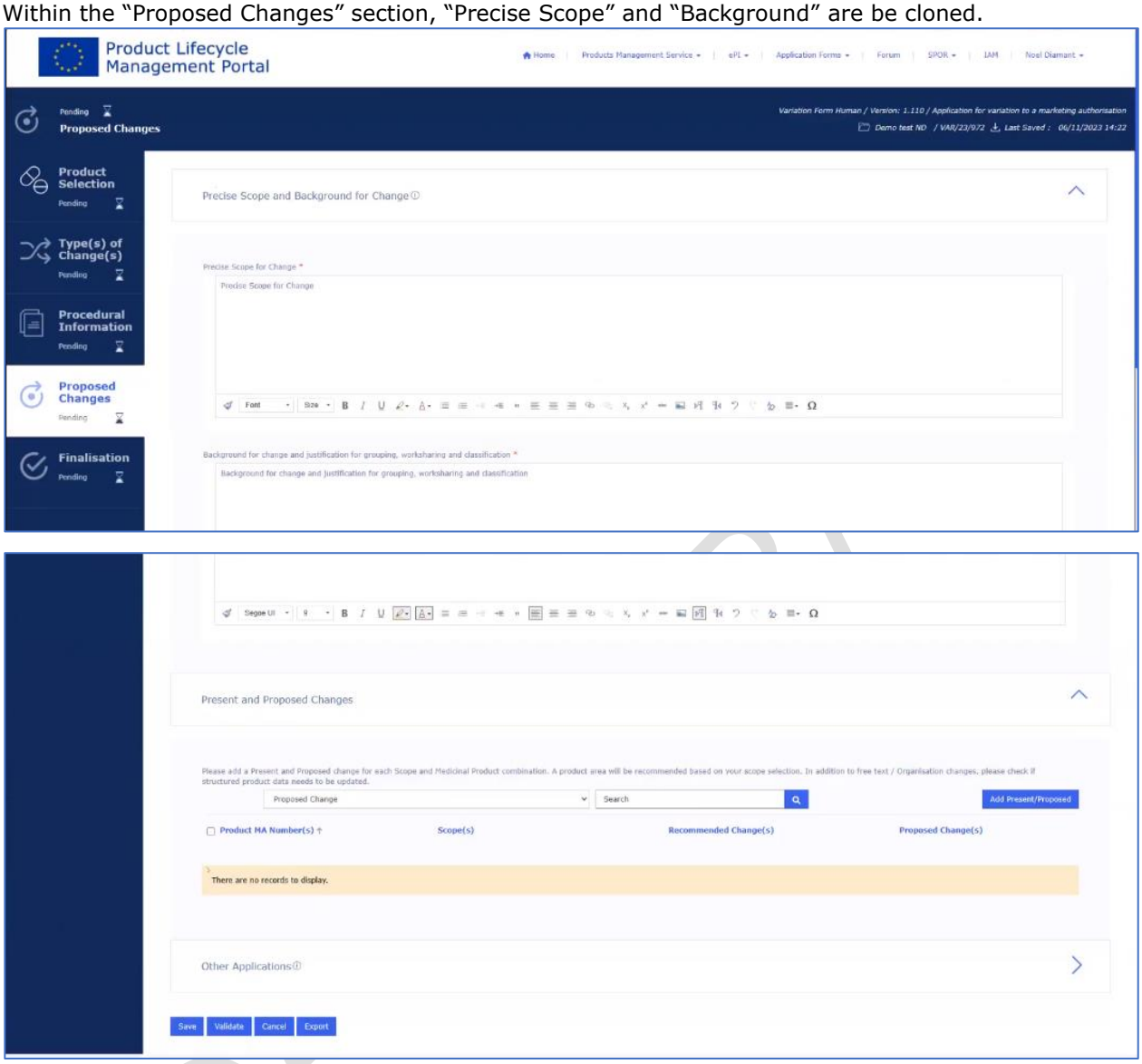
Procedural information will also all be cloned



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



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



- 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.
- 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. It is anticipated that this feature will be available

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)

2.2. Product Selection

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

2.2.2. 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;

2.2.3. Industry users with an active EMA account and with the eAF Applicant Coordinator role can edit 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. Please note that this feature is not yet available as only CAP products are available in the system.

4. Sign into the PLM Portal - eAF
5. 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
6. Click on Application Forms

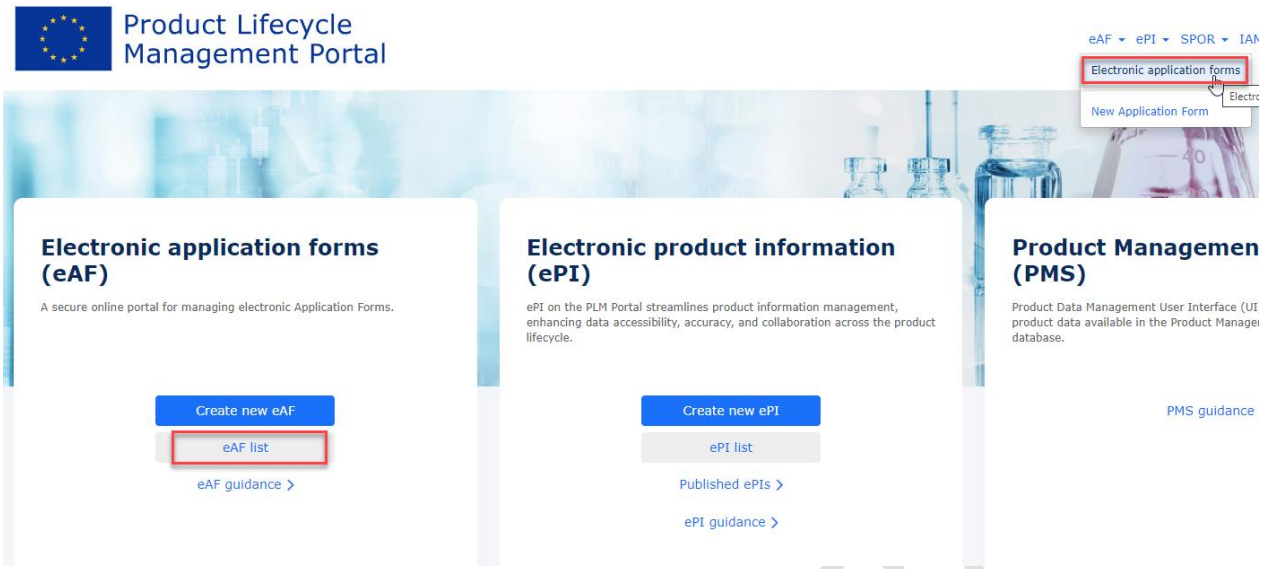


Figure 12 - Application Forms

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.*

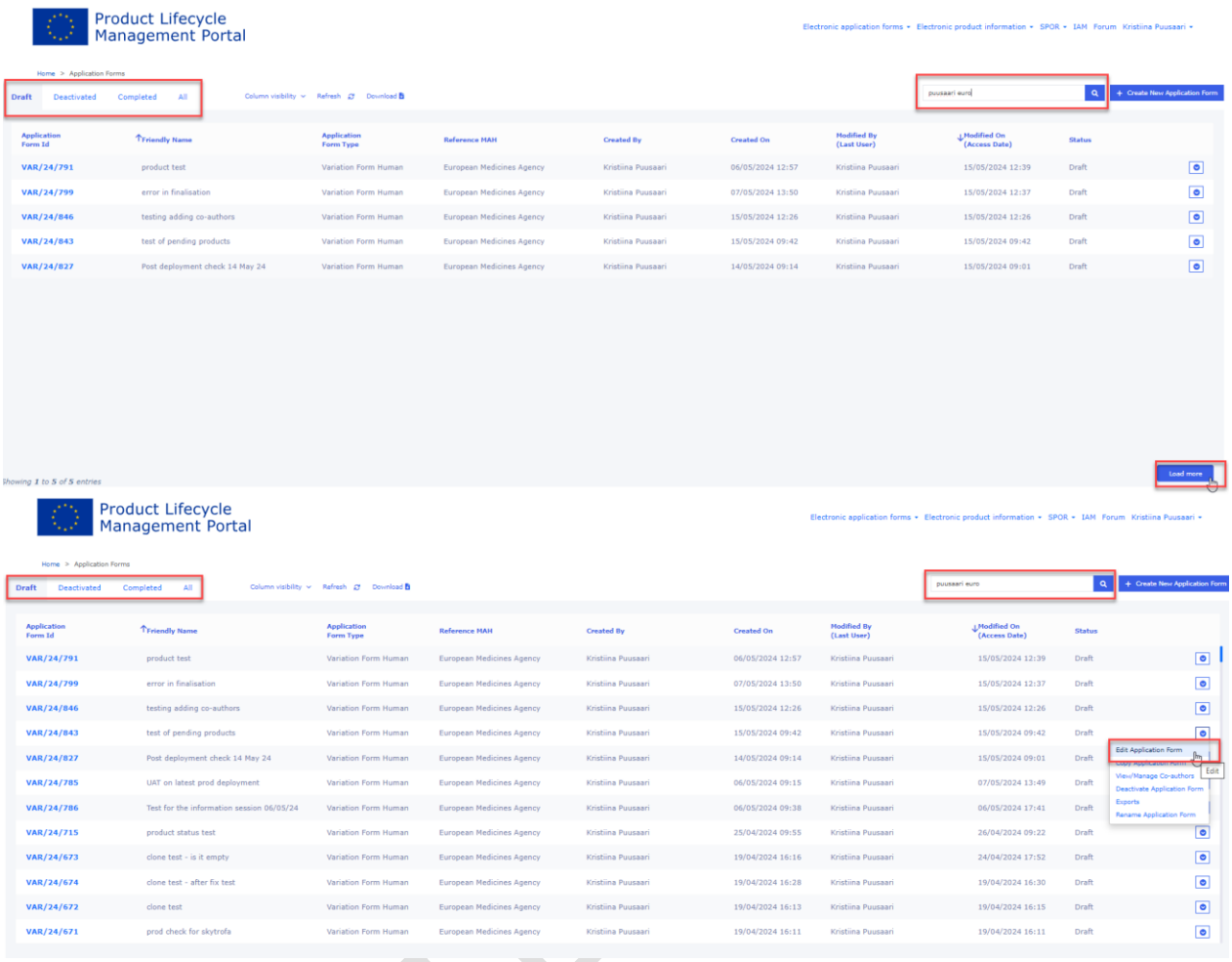


Figure 13 - List of Application Forms

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, 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. In order 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. If you wish not to change the modified by, do not click 'save' anywhere, just cancel to come out of the form.

Click the down arrow 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 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)** (UAT) eAF Applicant Contributor	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	**NCA user(s)** (UAT) eAF Competent Authority User
Draft	- Edit Application Form - View/Manage Co-authors	- Edit Application Form - Exports - Deactivate Application Form - Copy Application Form* - View/Manage Co-authors		
Deactivated	- View Application Form - View Co-authors	- View Application Form - View Co-authors - Exports - Copy 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 - Copy Application Form* - Deactivate Application Form		
All	Operations depend on the Status of the Application Form. Refer to the above operations and statuses			
*	Feature not currently working			

Description of the different operations:

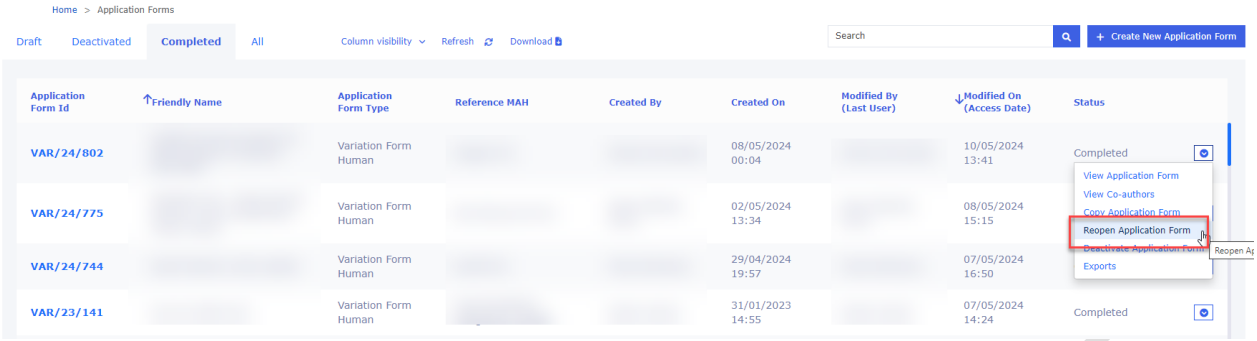
- *Exports – export generates a PDF eAF document which contains an FHIR XML attachment,*
- *View Co-authors (available in the 'Deactivated and Completed tabs) – provides a (read-only) list of all previously added co-authors onto a given Application Form;*
- *View/Manage Co-authors (available in the 'Drafts 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 '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;*
- *Copy Application Form – it creates a separate copy of that Application Form.* ***New****;*
- *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 currently* ***not available*** *.*

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

2.2.3.1. 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 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'.



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.

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

The copy 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.

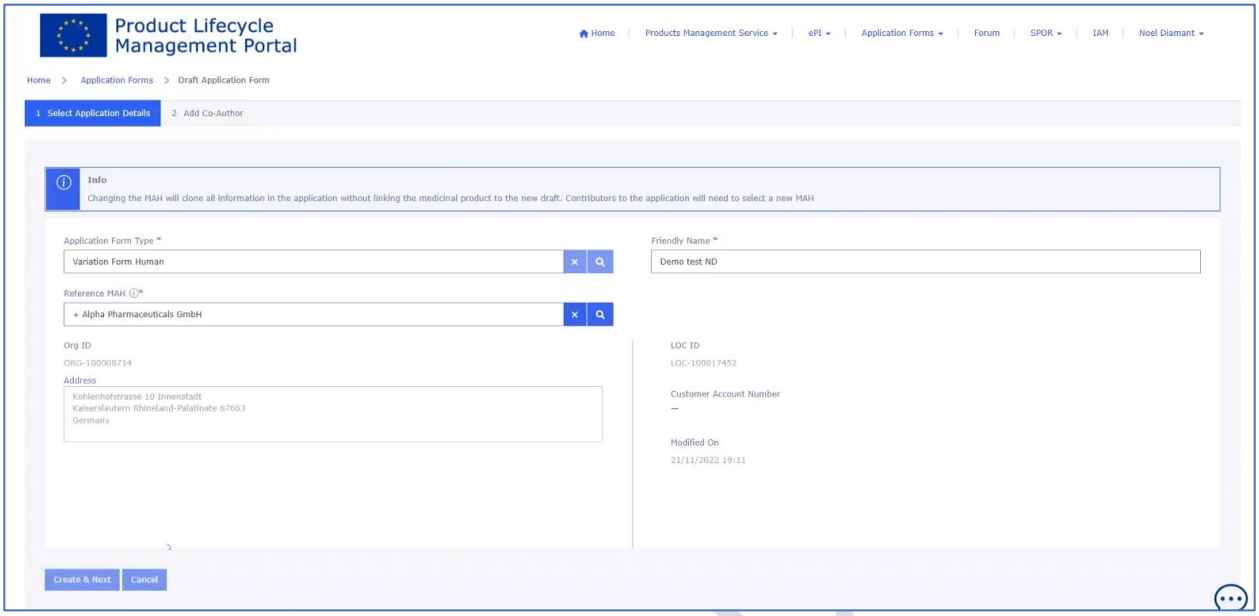
Upon clicking the Copy application option, a new window will open where the user will need to give the form 'Friendly name' and select the MAH – follow the same steps as when you create a new application with filling in the application particulars.

This feature caters to two different scenarios:

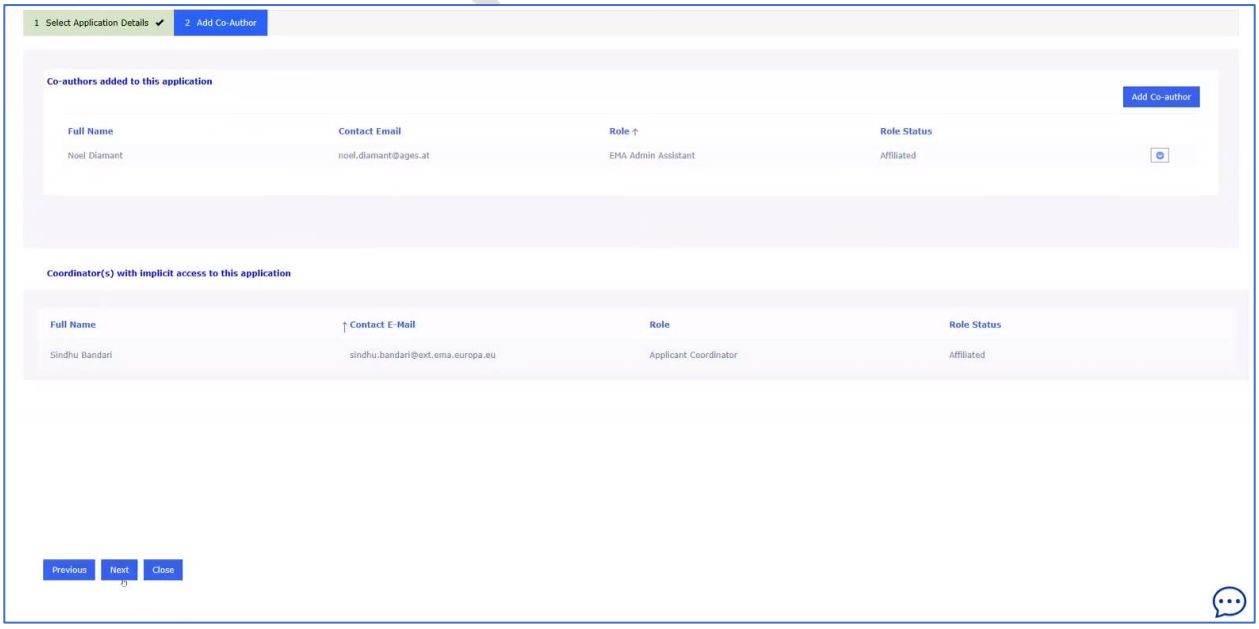
3. The first scenario addresses situations where an application has been previously submitted, however subsequent requests for information or alterations have arisen. Users may want to retain the original, finalised version while making modifications for resubmission or to address queries. This functionality 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.

4. 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 worksharing variation containing all or some of the same products as in previous application. Occasionally, it

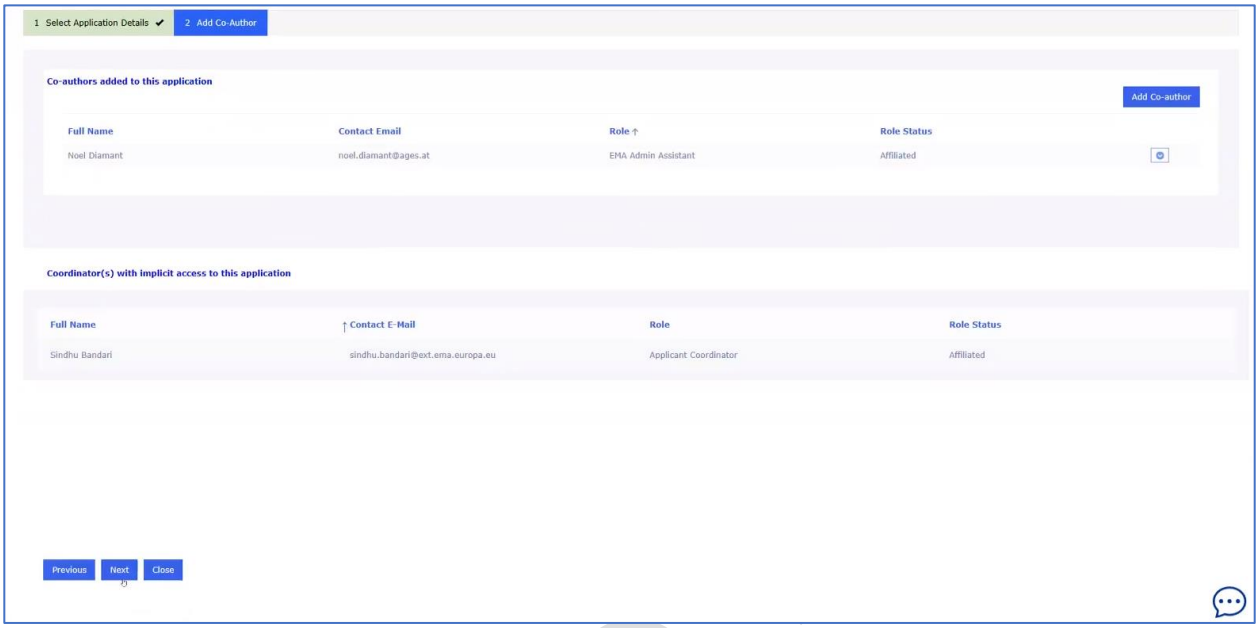
might be necessary to change Marketing Authorisation Holder (MAH) and access limitations might prevent the cloning of products, ensuring adherence to security protocols, and consequently, only other relevant information will be cloned.



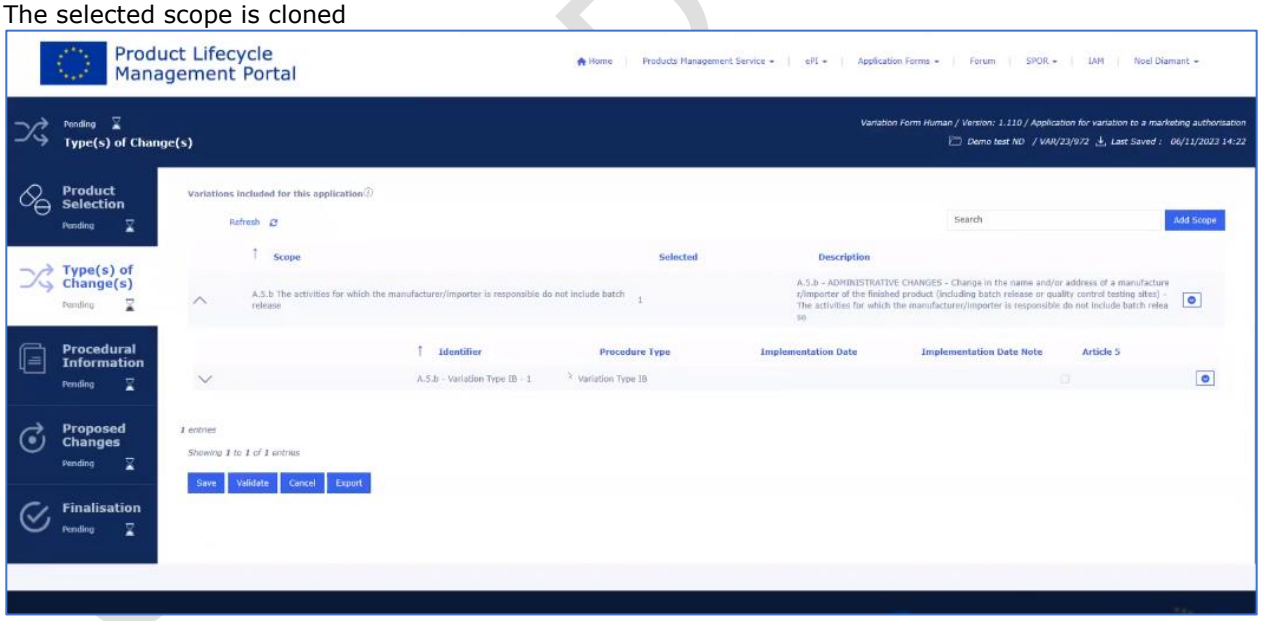
- Upon selecting "Create and Next," the process involves recognising the user initiating the cloning procedure, possessing inherent access to the application. Within the organisation, individuals holding a coordinator role have overarching visibility into all applications, thus eliminating the necessity 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.



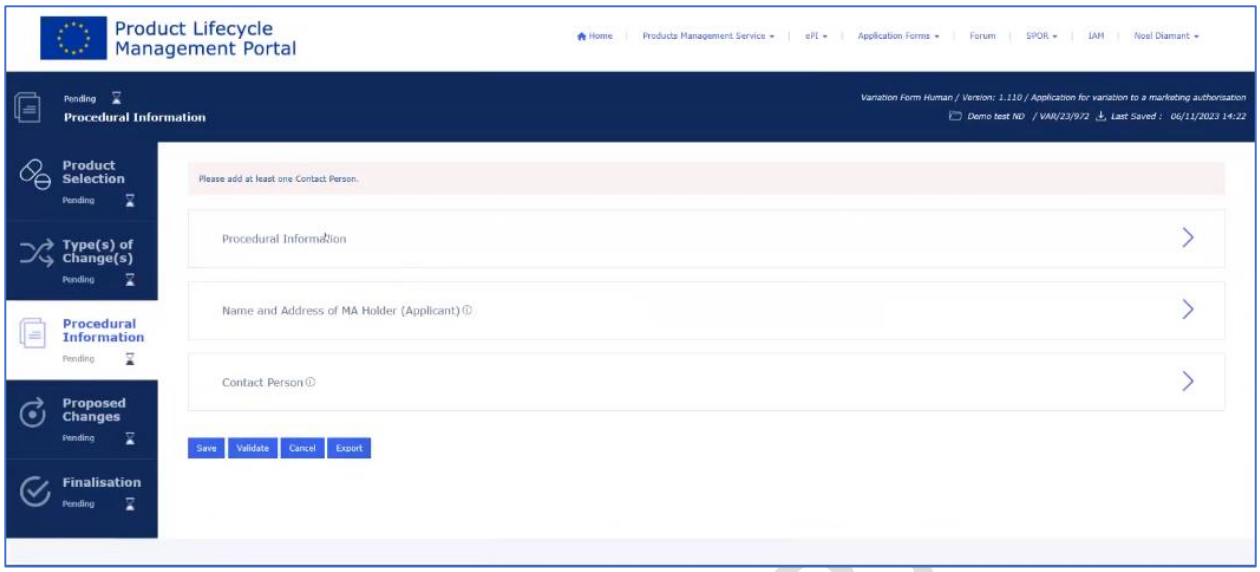
- Upon completion of these setup configurations, click on the "Next" button to start a comprehensive duplication process. This includes replicating all previously entered data—such as products, scopes, and proposed changes—ensuring the transfer of all relevant information to the newly created clone.



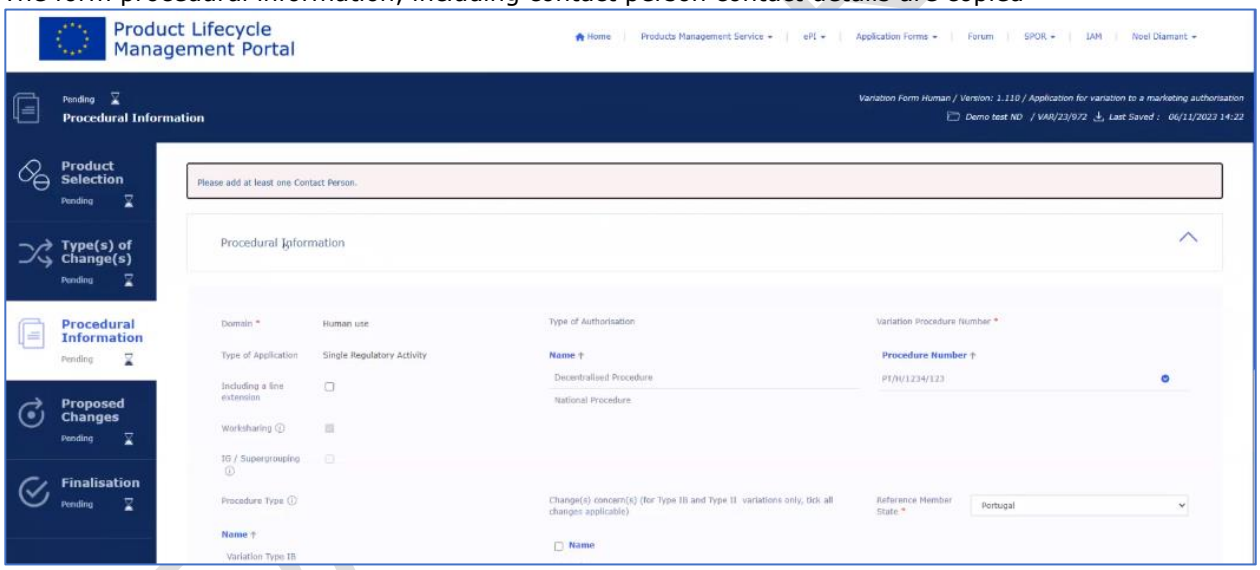
The selected scope is cloned



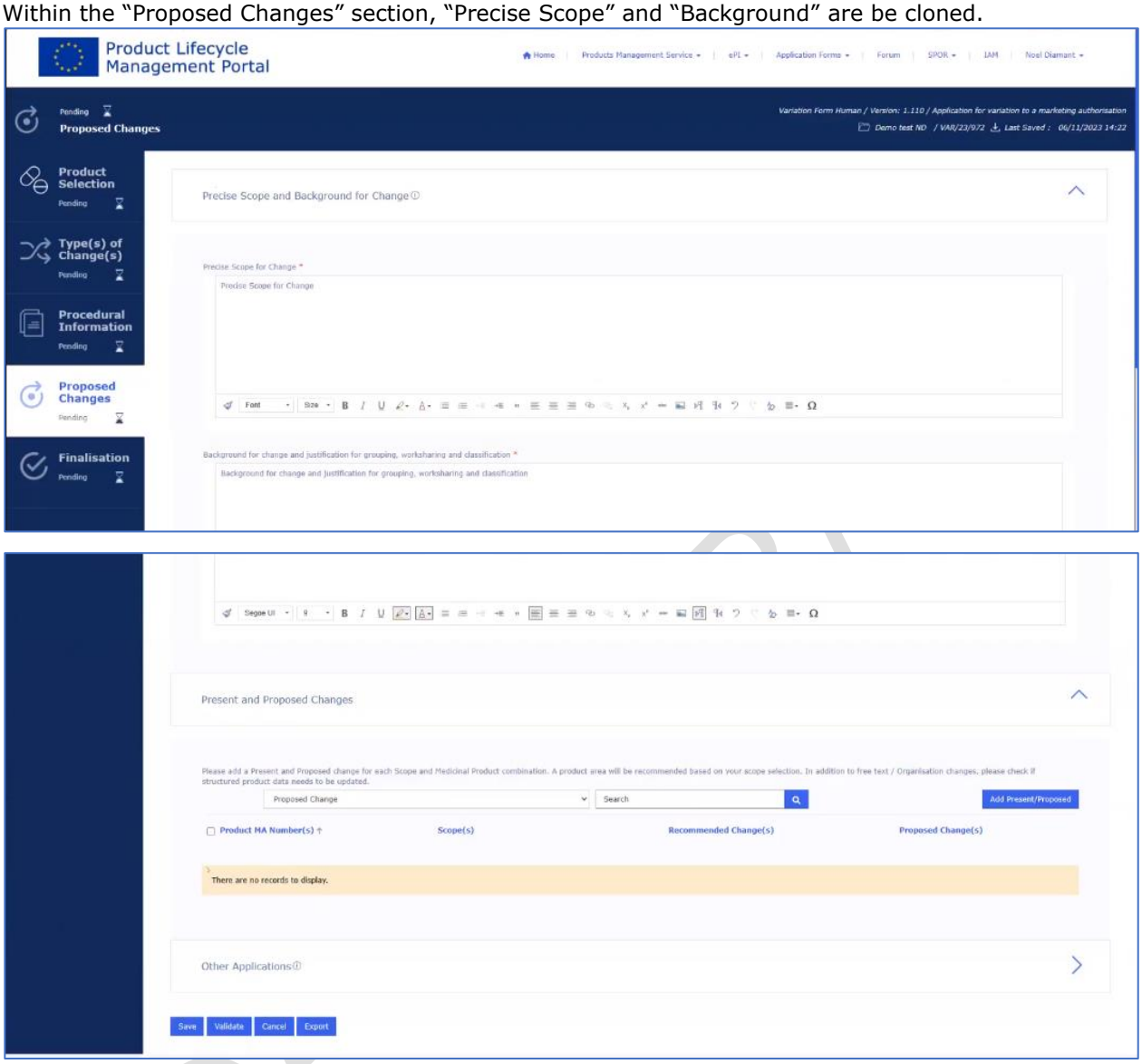
Procedural information will also all be cloned



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



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



- 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.
- 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.

2.2.5. Delete form function

The delete form function is not yet available. It is anticipated that this feature will be available

2.2.6. How to add a product in 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 products from an Application Form.

The adding of products is the first step of an Application form. Refer to the Products Selection step on the left-hand side of the menu.

The product Selection tab is comparable to the Section 2 of pdf eAF.

1. Access an existing or create a new Application Form. See sections 1.1.1, 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 + Add Product button.

   Please note that the 'search' field with the magnifying glass is not a search field but find products, but to 'filter' a list of already selected products (this can be only used when editing a form that already has some products selected). Products cannot be searched/added using this field.

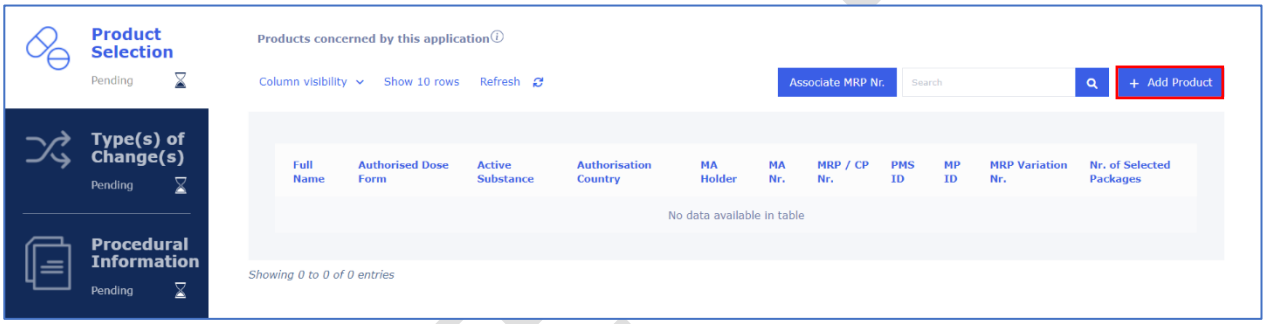


Figure 14 - Add Product

In the Select Product subpage, select the applicable product(s).

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.

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.

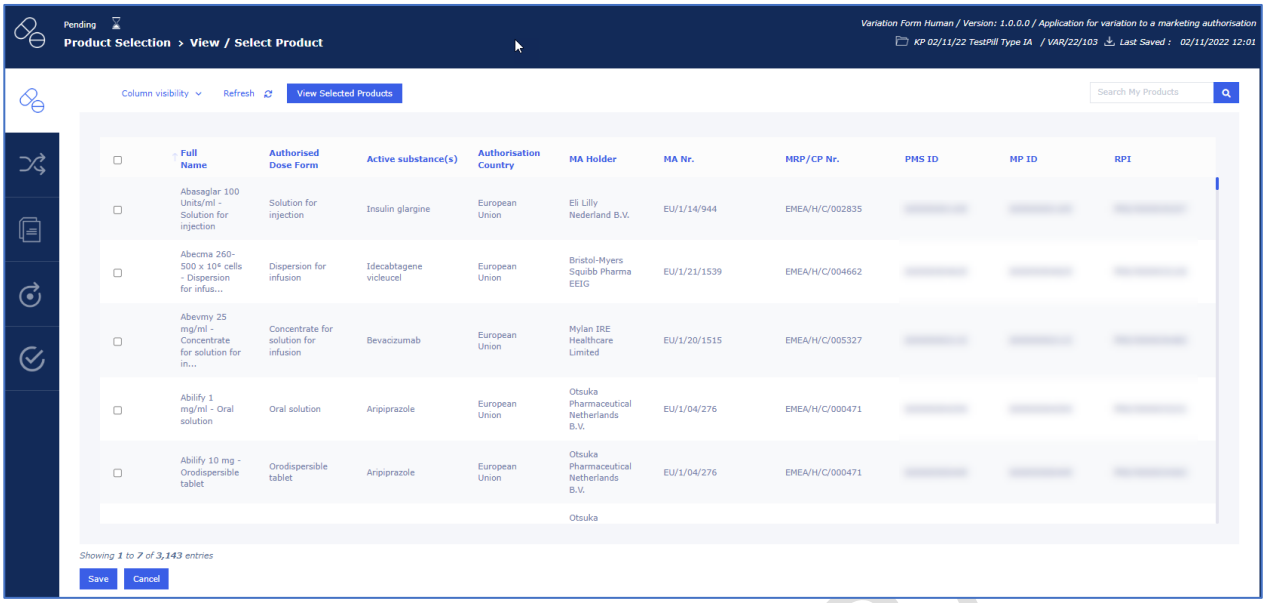


Figure 15 - List of Products

If you are adding a larger number of products you can click on View Selected Products to have a glance at the products you have selected in the previously. You may switch between that view and the View Available Products view to go back to the full list of selectable products.

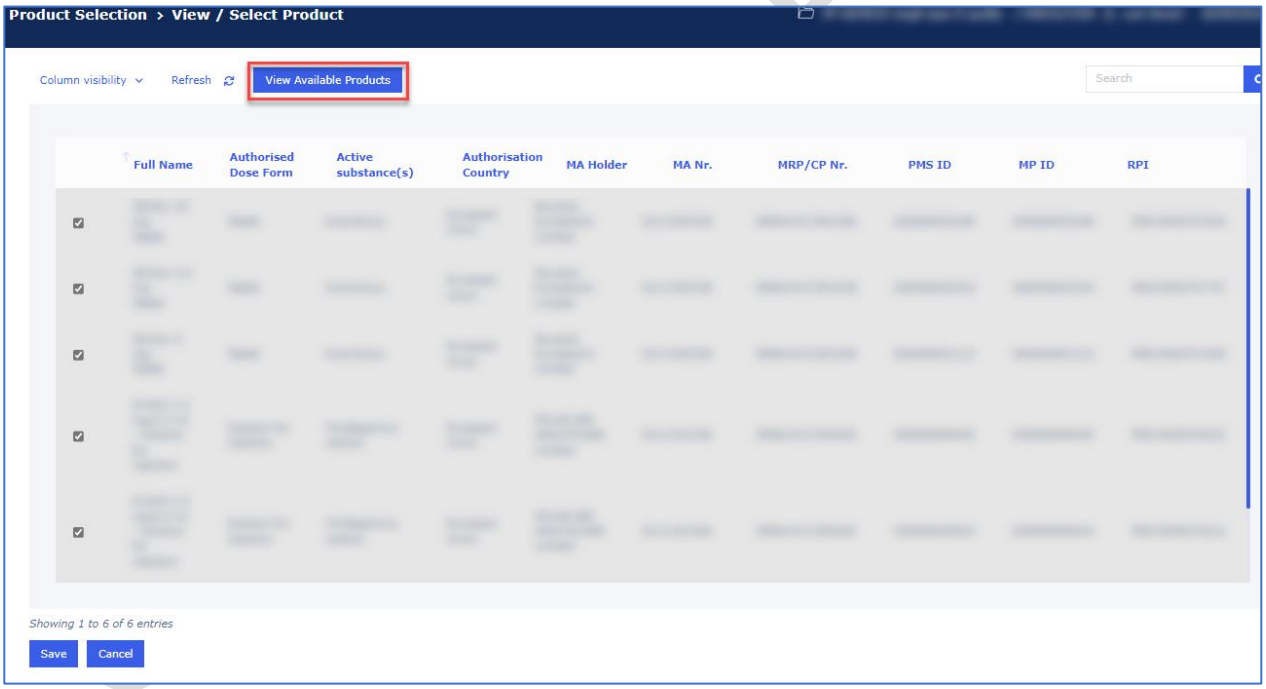


Figure 16 - View Available Products

If you do not find the product you are intending to select, click on the Refresh button. 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 (you will need to be signed in to see the list content). This will open a full list of authorised products.

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.

Click on the Save button

Back in the Product Selection page, you may wish to 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: there is 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 a number of the packages for each medicinal product in the last column.

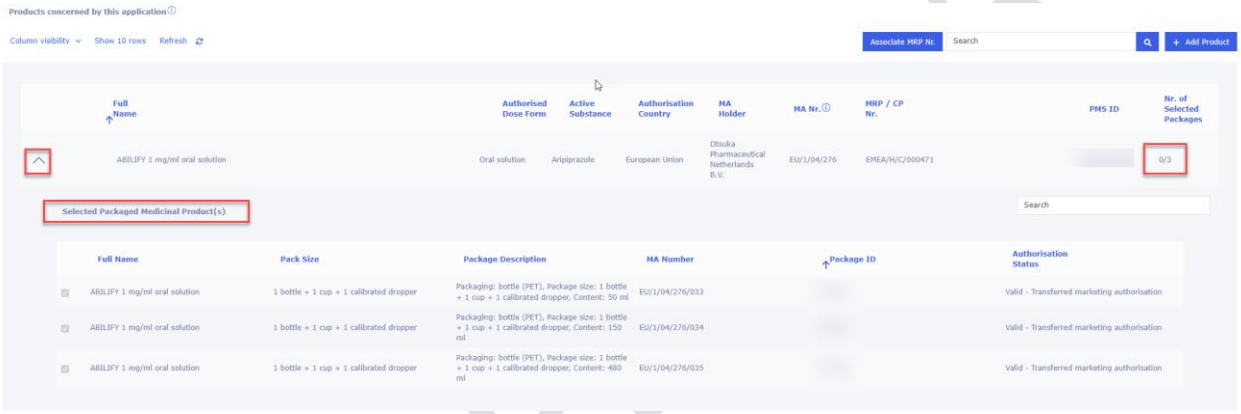


Figure 17 - Packaged Medicinal Product(s)

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 the medicinal product that you do not need, please click the 'Add product' button again and deselect (untick) the selected products not needed in this application and save the updated selection. The proceed as previously.

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.

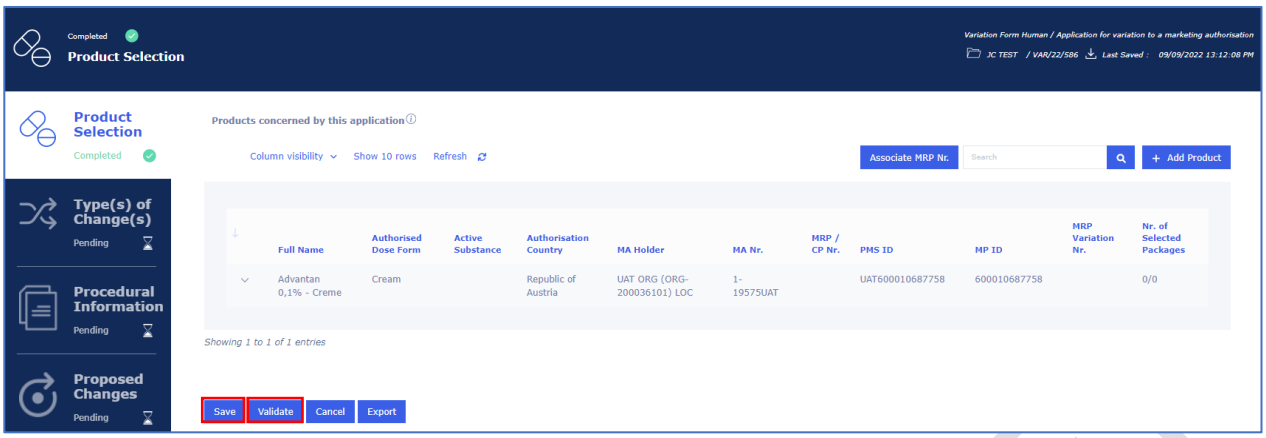


Figure 18 - Save and Validate Buttons

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

DISCLAIMER: the Associate MRP Nr. feature applies to NAP products only. As the first release of the variation eAF only contains CAP products this feature **must** not be used.

3. Access an existing or create a new Application Form. See sections 1.1.1, 2.1.2and 2.1.3 for further details
4. In the Product Selection page, click on the Associate MRP Nr. button

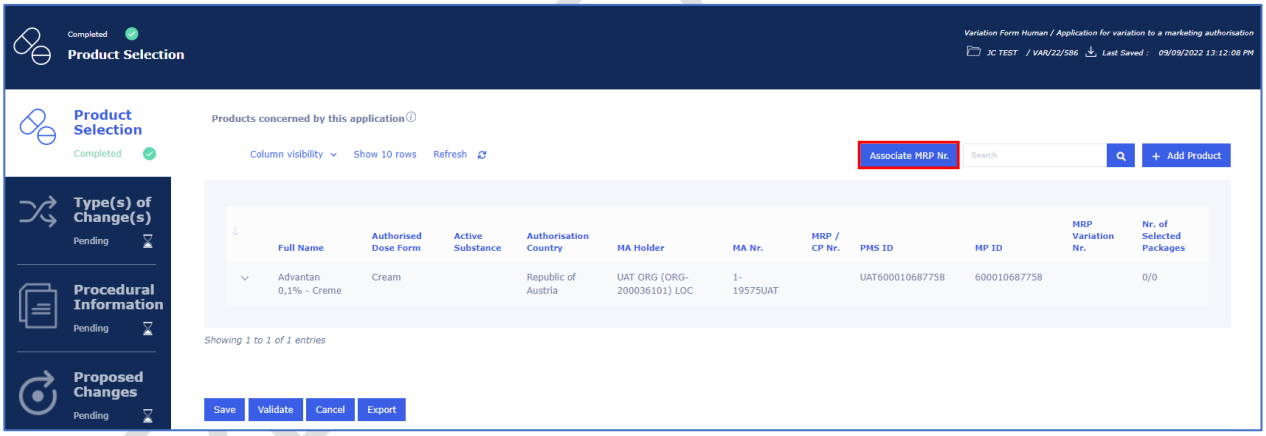


Figure 19 - Associate MRP Nr. Button

2.2.8. 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 1.1.1, 2.1.2and 2.1.3 for further details
2. In the Product Selection page, click on + Add Product

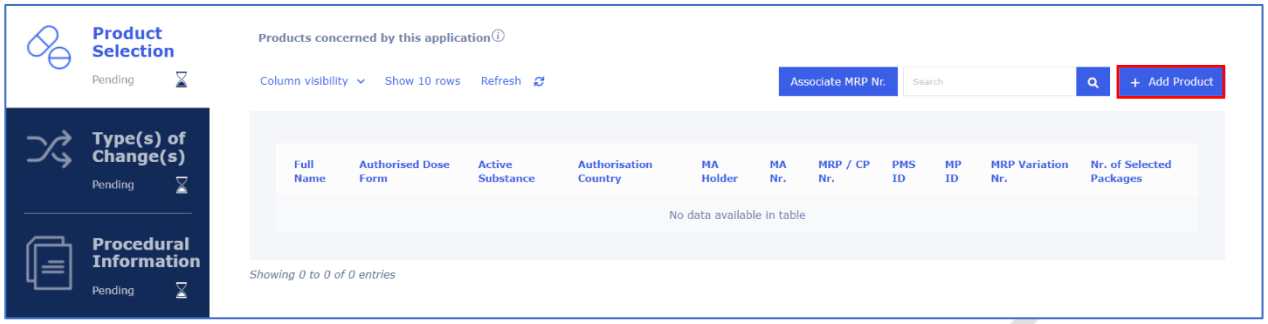


Figure 20 - Add Product

3. In the Select Product subpage, un-tick the product(s) you would like to remove/delete from the application form (you can click anywhere in the line, you do not need to use the tick box). You may want to use the search bar to further filter 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.

4. Click on View Selected Products to have a glance at the products you have tick marked. You may switch between that view and the View Available Products view to go back to the full list of selectable products.

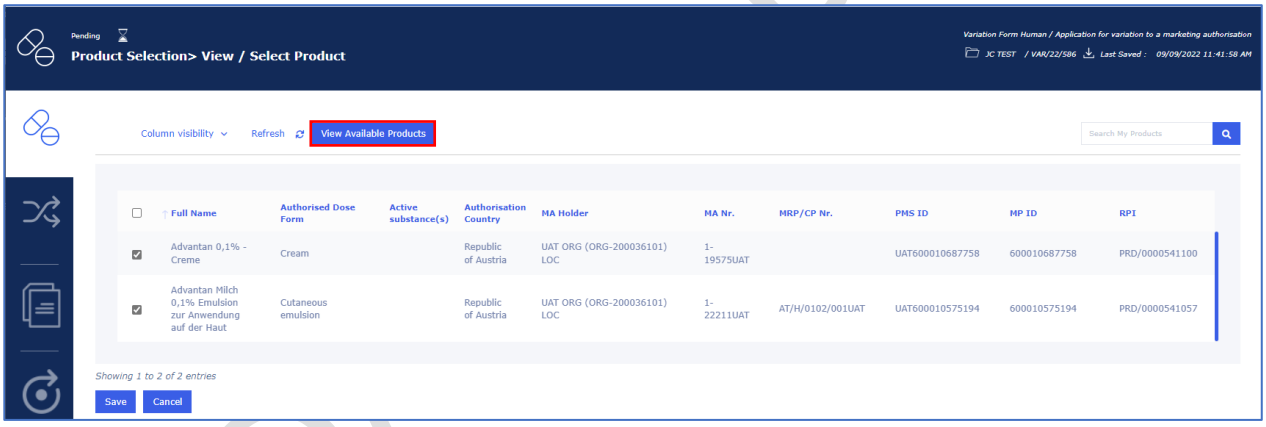


Figure 21 - View Available Products

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, click on the Save button. 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 (or even intended) to be able to select 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 products. The selection of presentations impacted will only 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. 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.

2.3. Type(s) of change(s)

2.3.1. How to add a variation scope 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 1.1.1, 2.1.2and 2.1.3 for further details
2. In the Type(s) of Change(s) page, click on Add Scope .

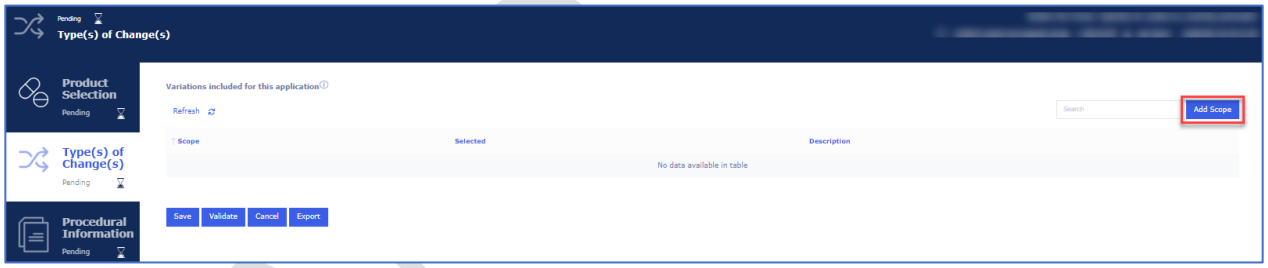


Figure 22 - Add Scope

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

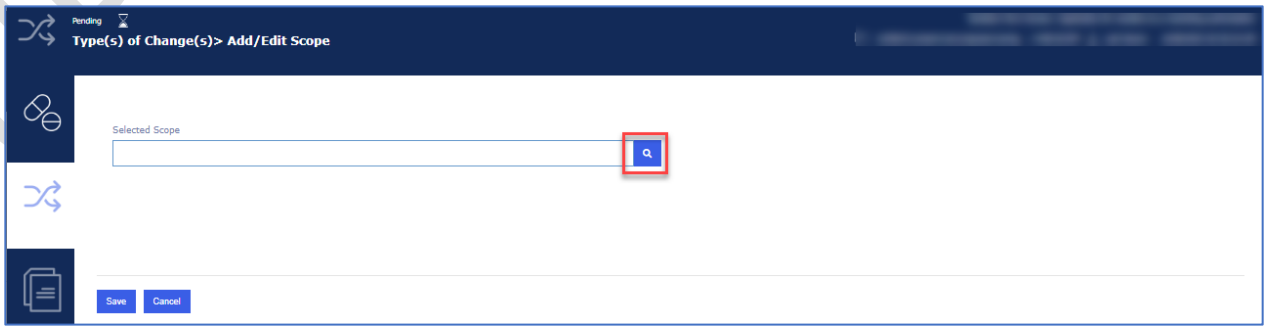


Figure 23 - Select Scope

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 24 - Example of Search using Classification Code

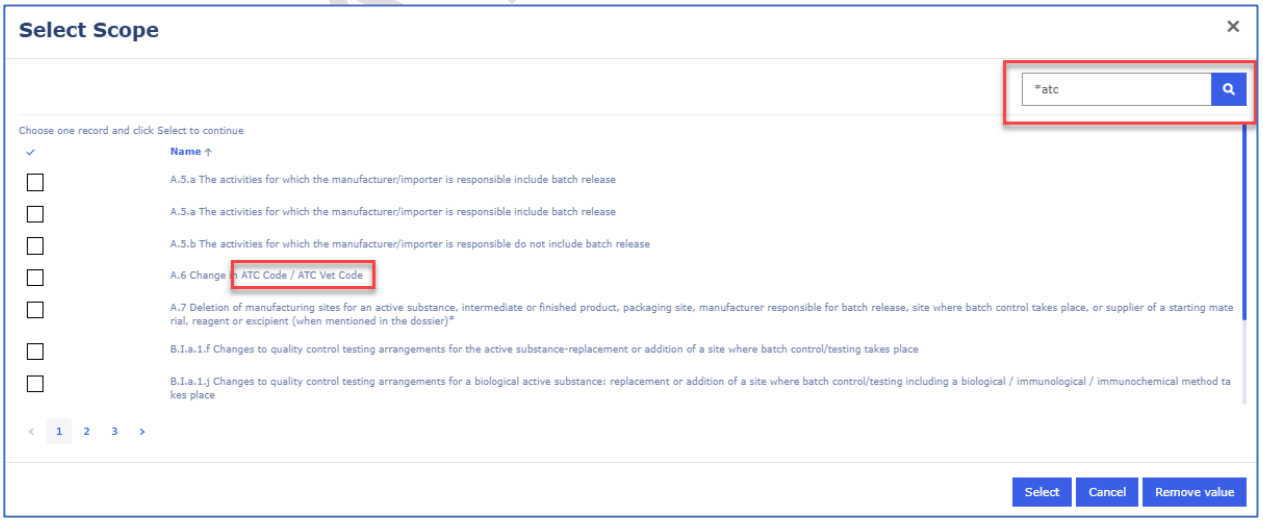


Figure 25 - Example of Search using Wild Card and Text

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.

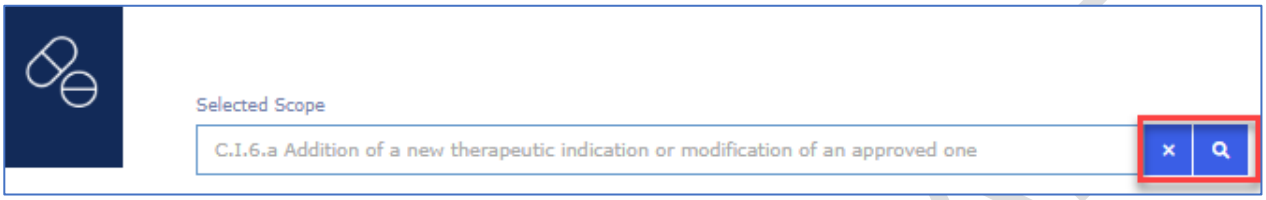


Figure 26 - Cancel and Select Scope

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

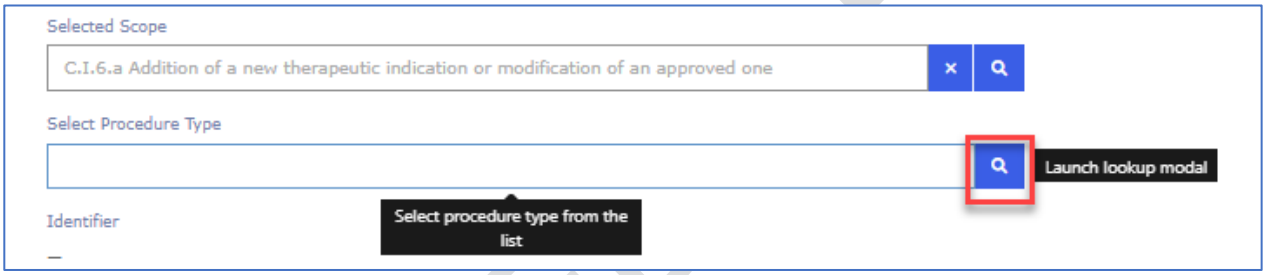


Figure 27 - Select Procedure Type

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 on the Select button to select the procedure type. If the procedure type you wish to select is not available, 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.

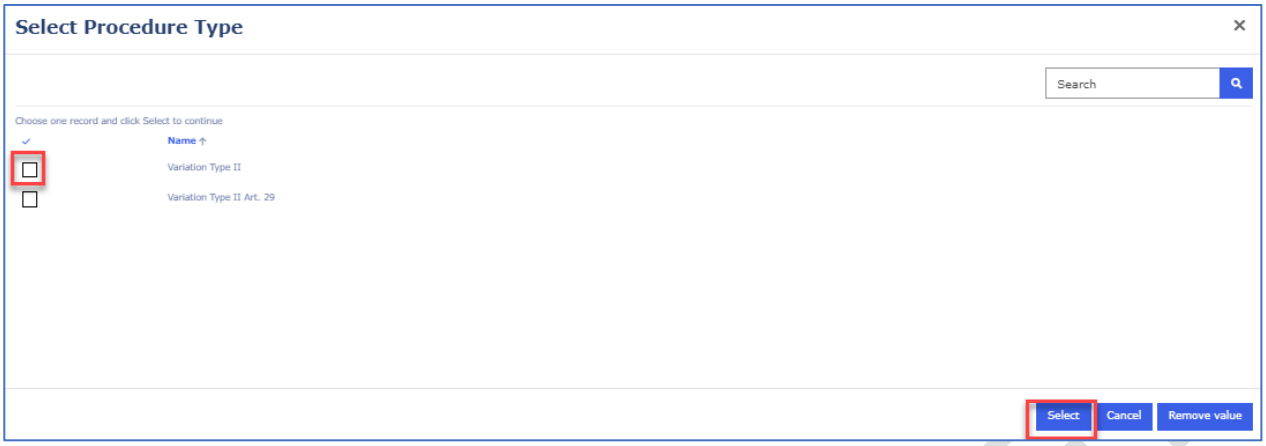


Figure 28 - Select Procedure Type

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

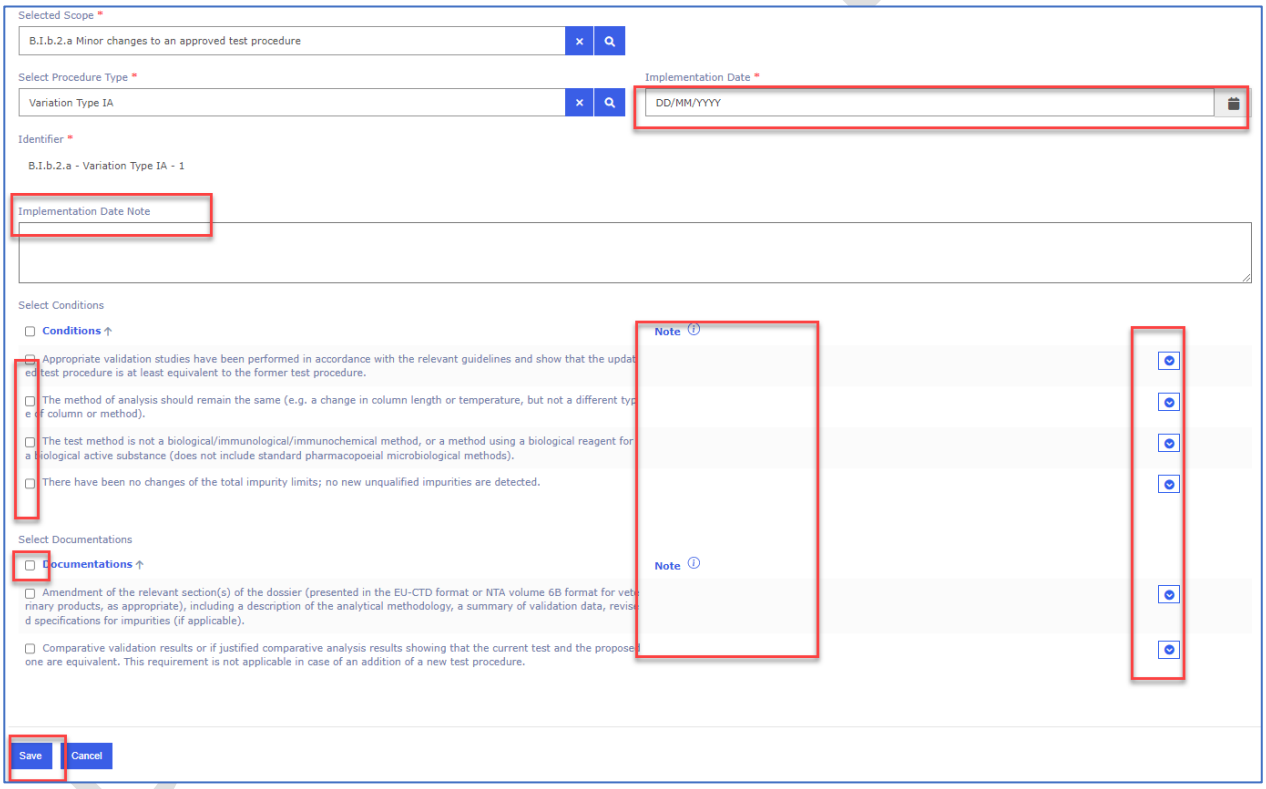


Figure 29 - Option Selection

For Type IA/Type IA_{IN} you need to add an Implementation date (either by selecting it from a calendar or by providing the date in format DD/MM/YYYY e.g.: 31/12/2022). 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 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 using the small arrow on the right-hand side. This will launch a free text field for note/justification.

NOTE: There is a known issue affecting the Conditions and Documentations, this may result in an error message saying that a note should be added if all conditions are not met/documentations are not provided. This may happen when the higher level multi select tick box is used to select all conditions and/or documentations at the same time. If this happens, simply use the same tick box to untick all and reselect individually.

Note that removing the scope or procedure type (using the x button) may 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

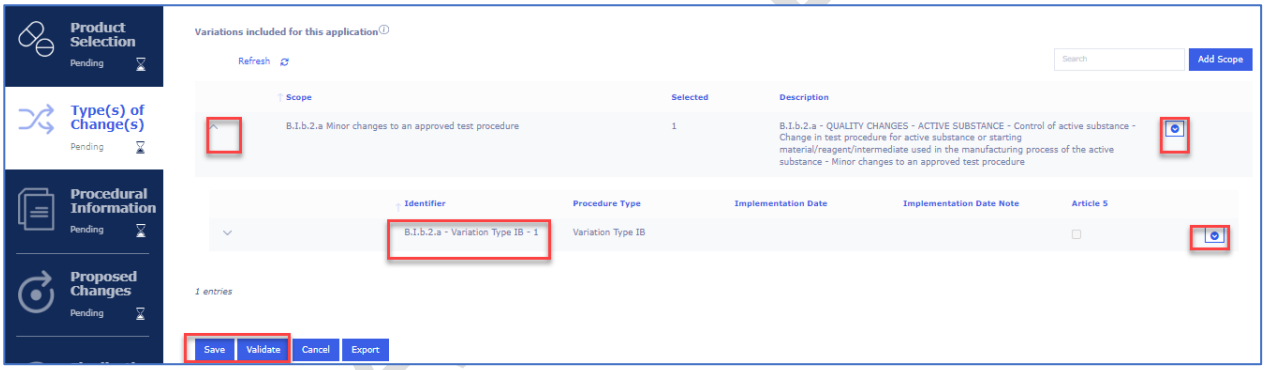


Figure 30 - Summary of Selection

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.

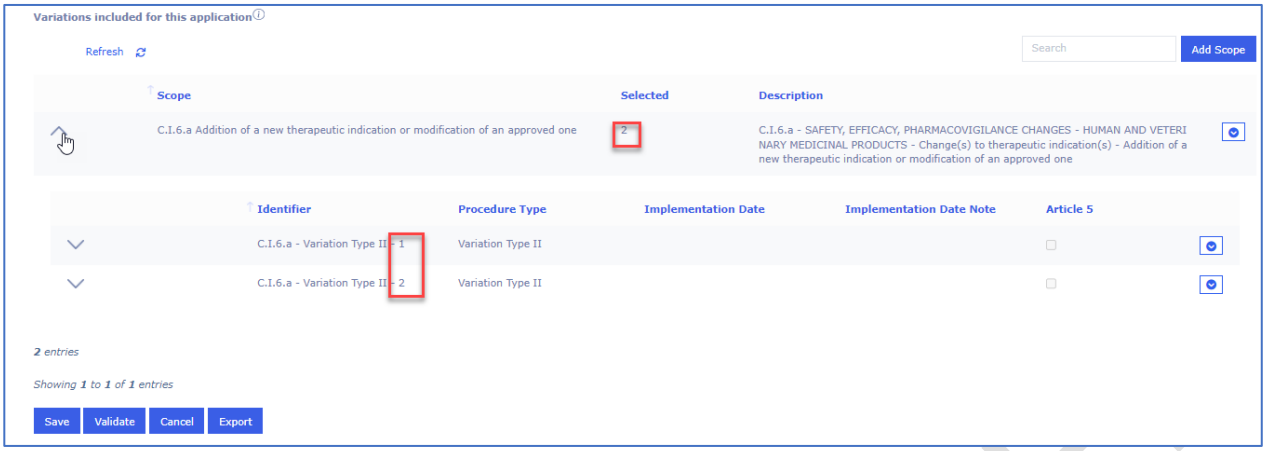
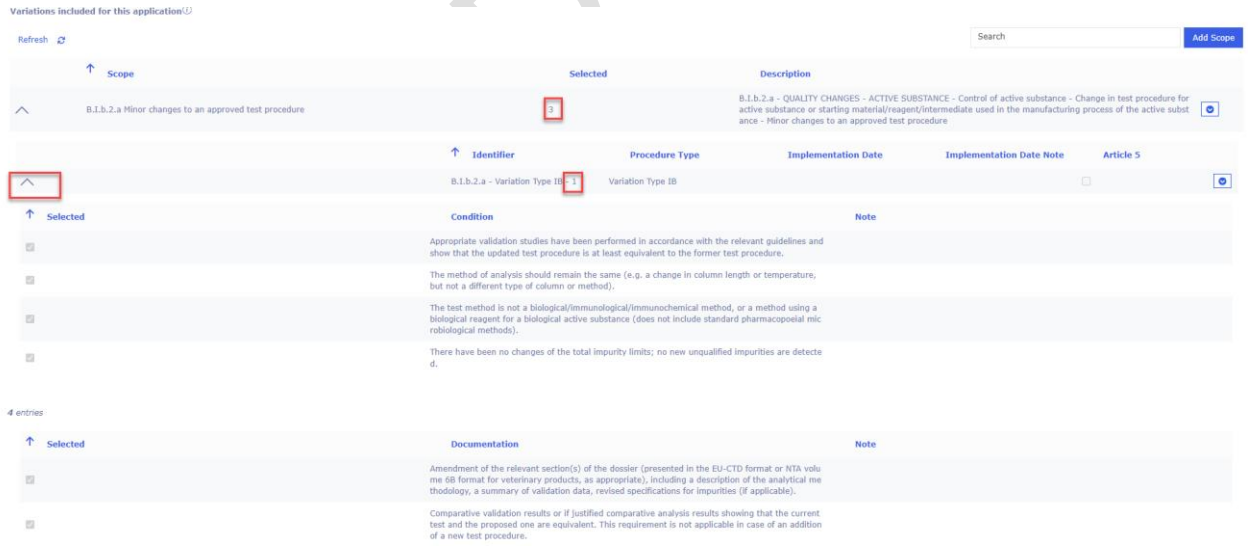


Figure 31 - Add Scope

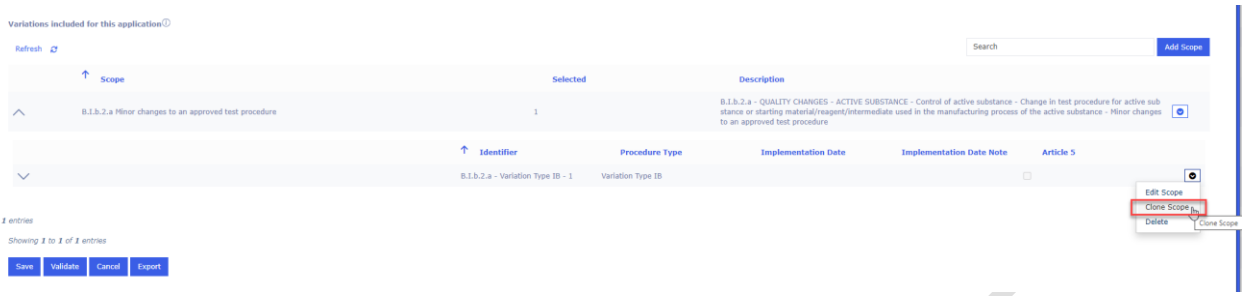
13. Click on the Save button to ensure that you save the changes you made i.e. to save the selected scope(s). You may want to click on the Validate button to change the status of this section to Completed.

2.3.2. Clone scope

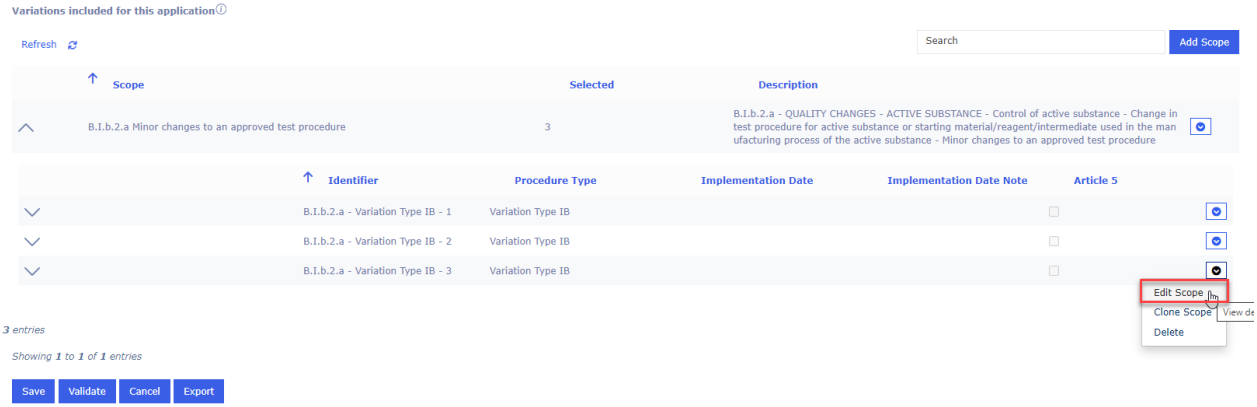
- In order to clone the scope, you will need to have added at least one scope in the form. View the added scope(s) and expand the details of the scope to 'clone scope'
- Click on the arrow on the left of "Scope" to have a full overview of the scope.



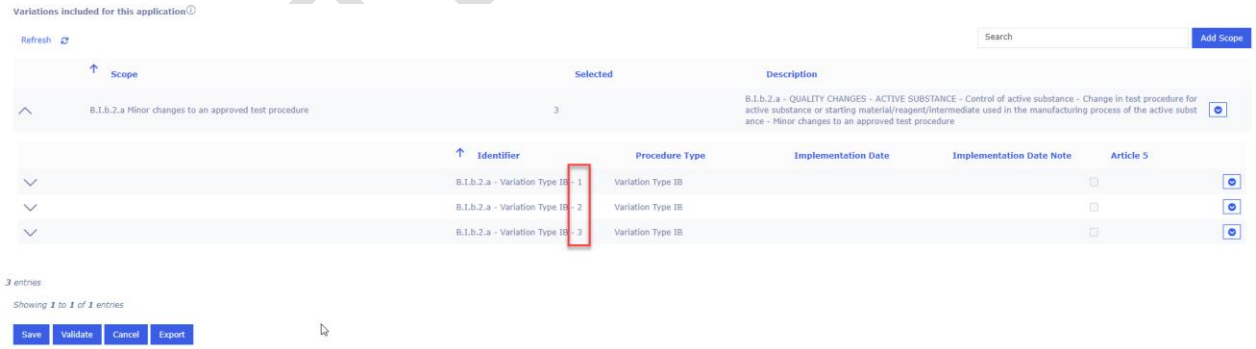
- Click on the button at the far right of the same row to select "Clone scope" option.



- 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 1.1.1, 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'.

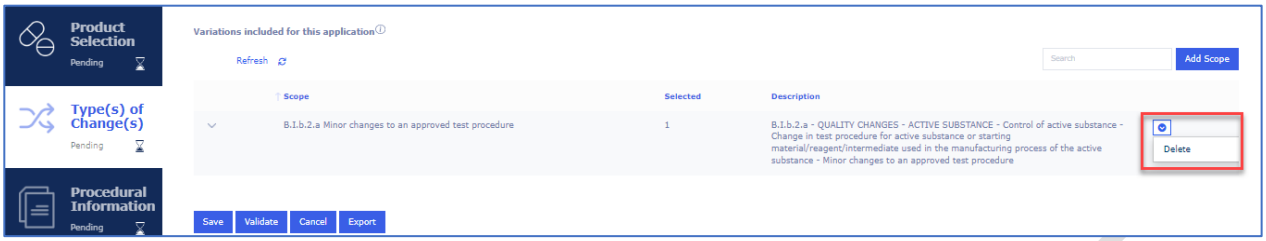


Figure 32 - Delete Scope

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/view' scope.

Figure 33 - 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.

3. Access an existing or create a new Application Form. See sections 1.1.1, 2.1.2and 2.1.3 for further details

4. 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'.

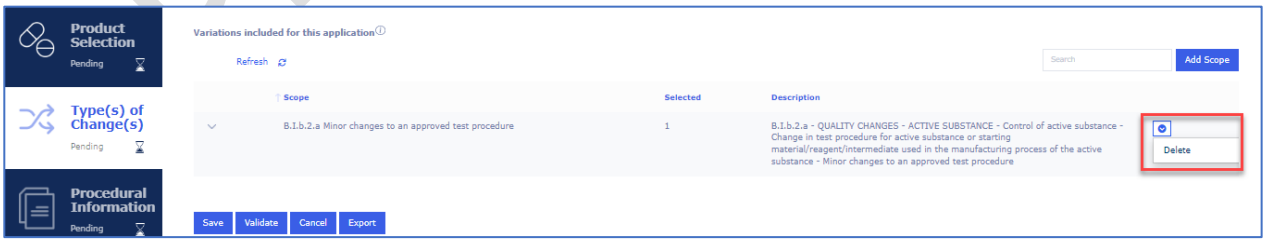


Figure 34 - Delete Scope

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/view' scope.

Figure 35 - Edit Scope

2.4. Procedural Information

The procedural information section is comparable to the 'section 1' of the pdf eAF. This section has been divided in 3 sub sections. You can expand the sections by clicking anywhere in each of the subsection fields (accordion).

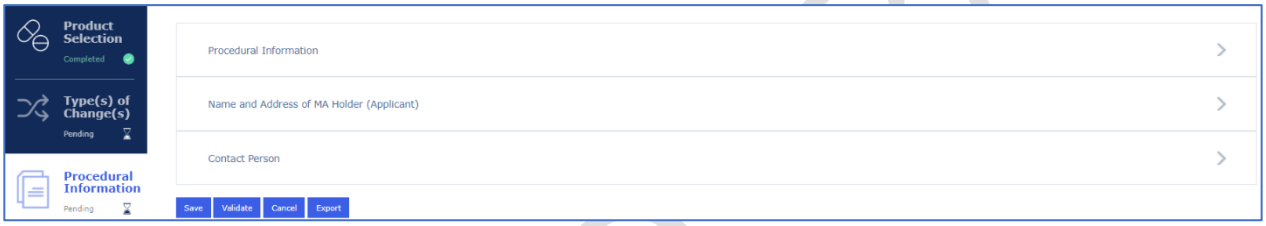


Figure 36 - Procedural Information Section Overview

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.

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.

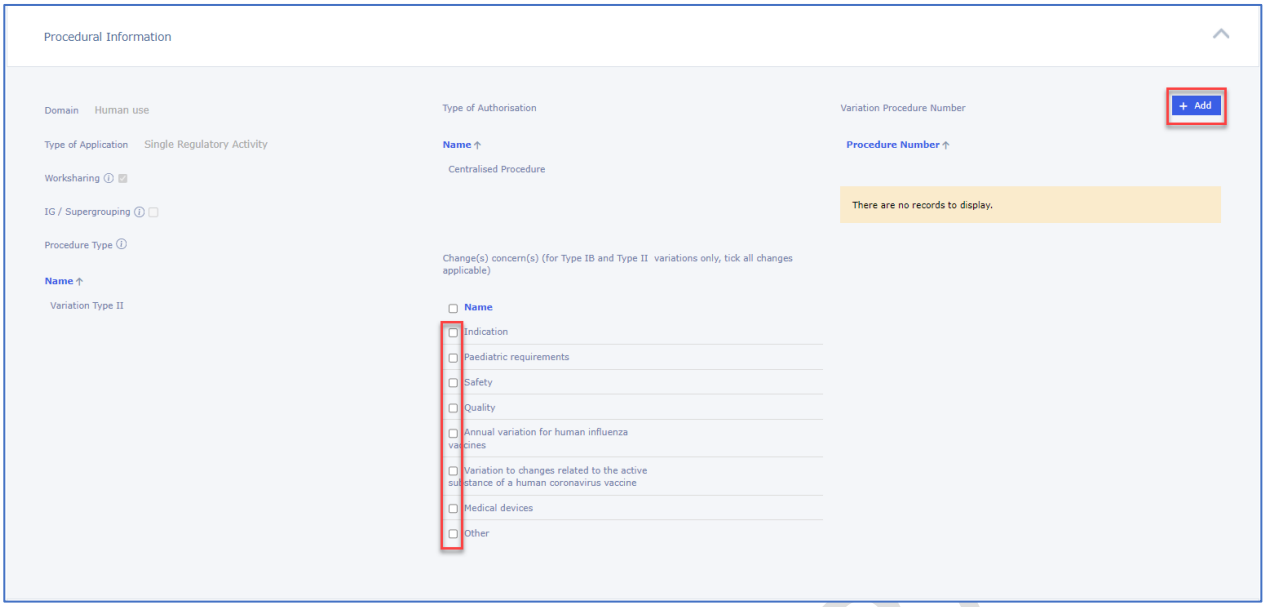


Figure 37 - Sub-section: Procedural Information

- *Domain: This is always 'Human Use' as the variation form 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. 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.*
- *IG/Super grouping; If more than one CAP 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). For now, this is always Centralised Procedure as non-CAPs are not yet available in the system. If you need to submit a work-sharing application containing both CAPs and NAPs (MRP/DCP/NP), please use the pdf format eAF only.*

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

- *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.*
- *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.*
- *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.*

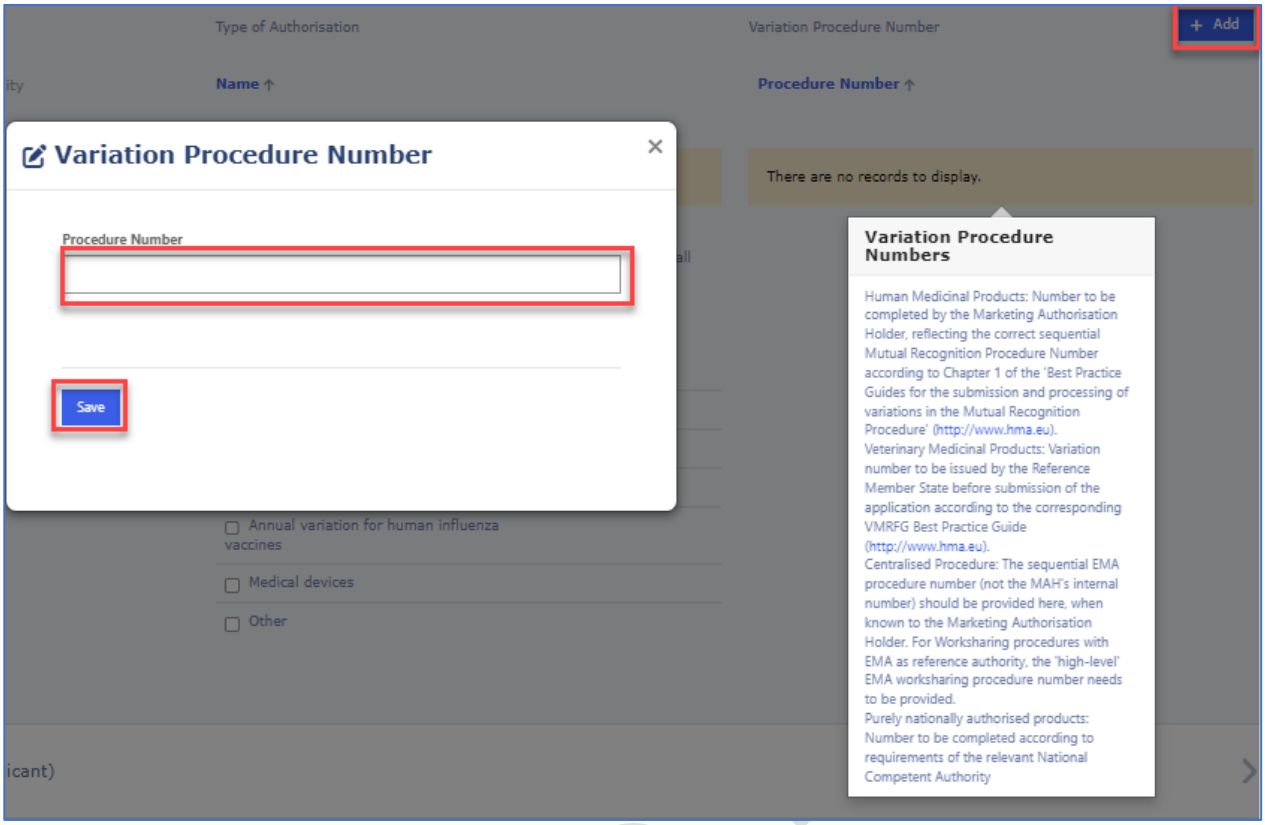


Figure 38 - Variation Procedure Number

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.

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

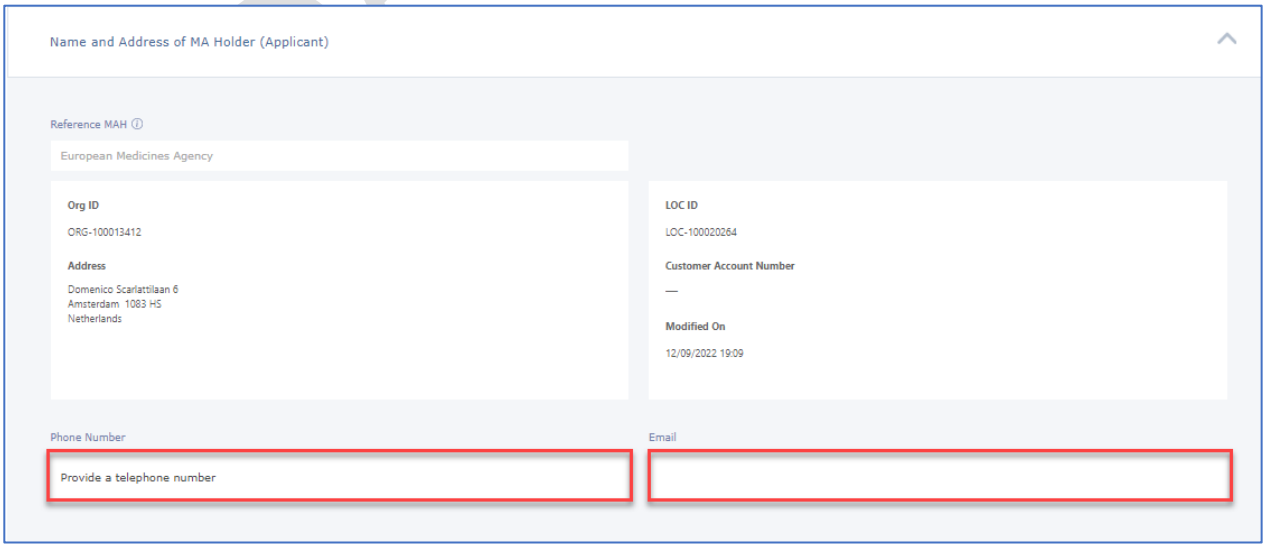


Figure 39 - Name and Address of MA Holder (Applicant)

2.4.3. Contact Person

The contact person field is not auto filled 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: there is a known issue which displays also some non-active locations for the organisations in the Contact person section.

1. Click the + Add button

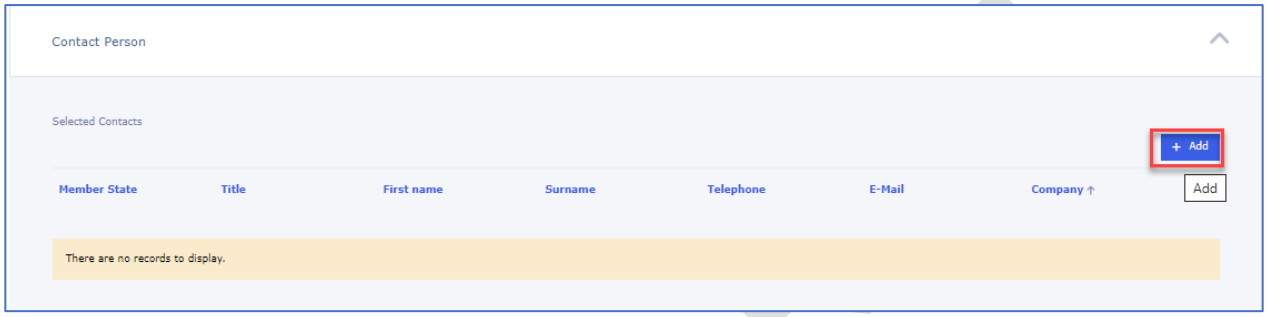


Figure 40 - Contact Person

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 Centralised Procedure applications, the Member State for the contact is always European Union and it is by design auto-filled and cannot be changed. There can only be one contact person for CP applications.

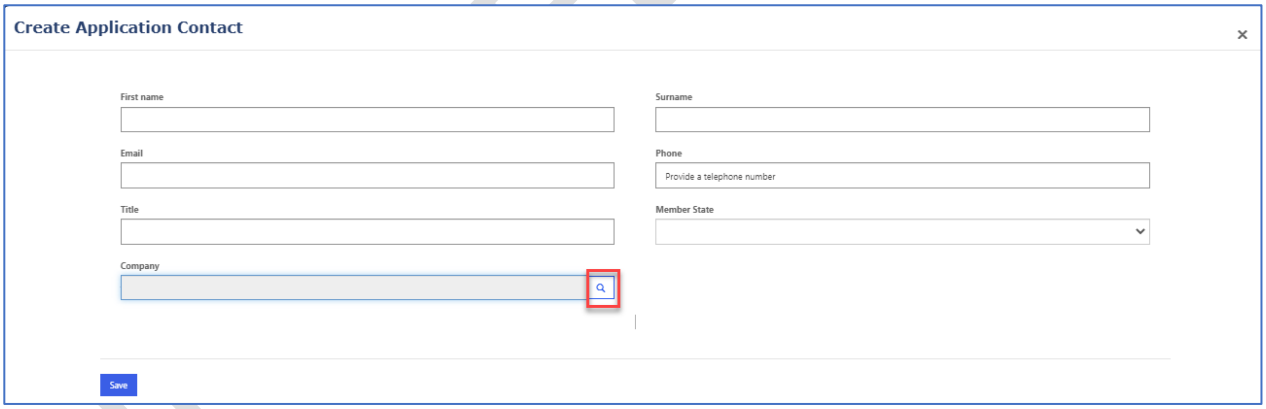


Figure 41 - Create Application Contact

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

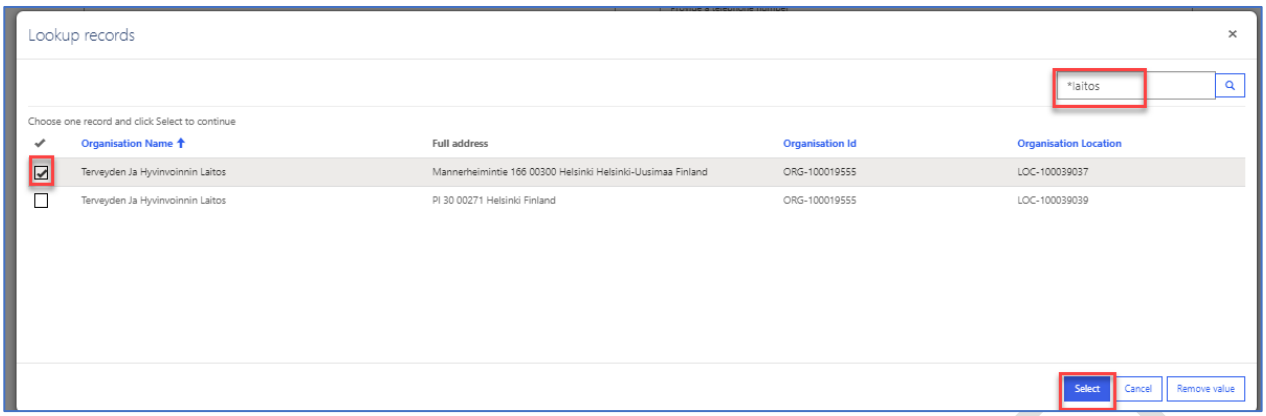


Figure 42 - Lookup Records

4. Click on the Select button and you will be taken back to the Create Application Contact page
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.

The Proposed Changes section is divided in 3 subsections. You can expand the sections by clicking anywhere in each of the subsection fields. Each of the sections can be saved individually to prevent any loss of data.

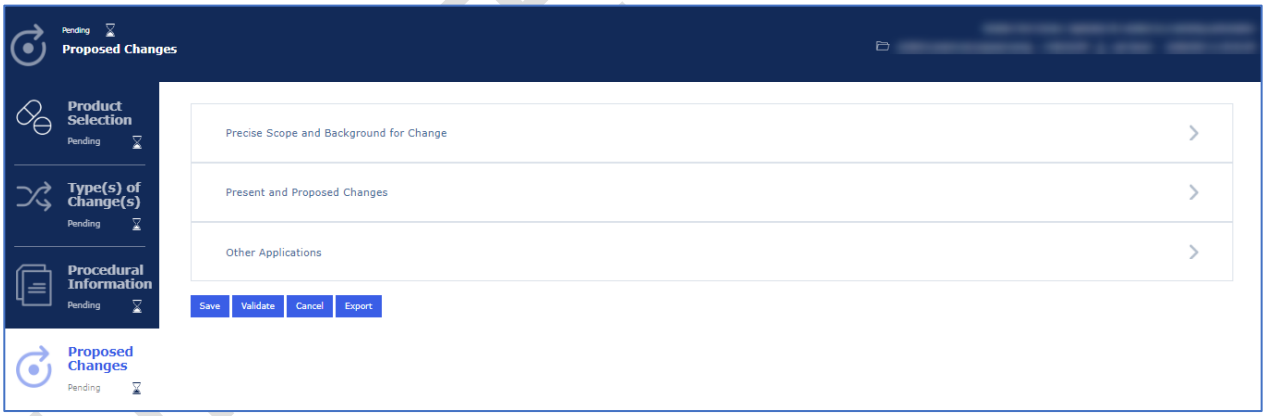


Figure 43 - Proposed Changes

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 1.1.1, 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.

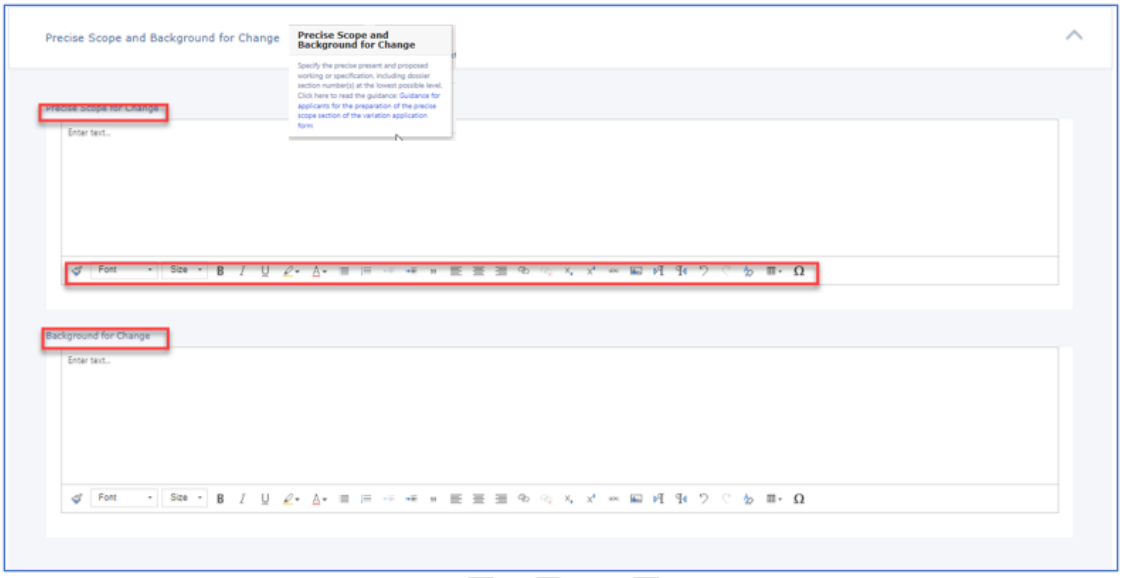


Figure 44 - Precise Scope and Background for Change

You can save your changes at any time, but please note that this will close the subsection which needs to be reopened to continue editing.

2.5.2. Present and Proposed Changes

NOTE: The system creates an empty row in this table when content is saved or when Add Present/Proposed is pressed and then cancelled. This not a bug but a technical feature of the system. In order to be able to save the changes, at different points of time, creation of an empty row is inevitable, however, the empty row can be easily removed or edited using the arrow at the end of the empty row.

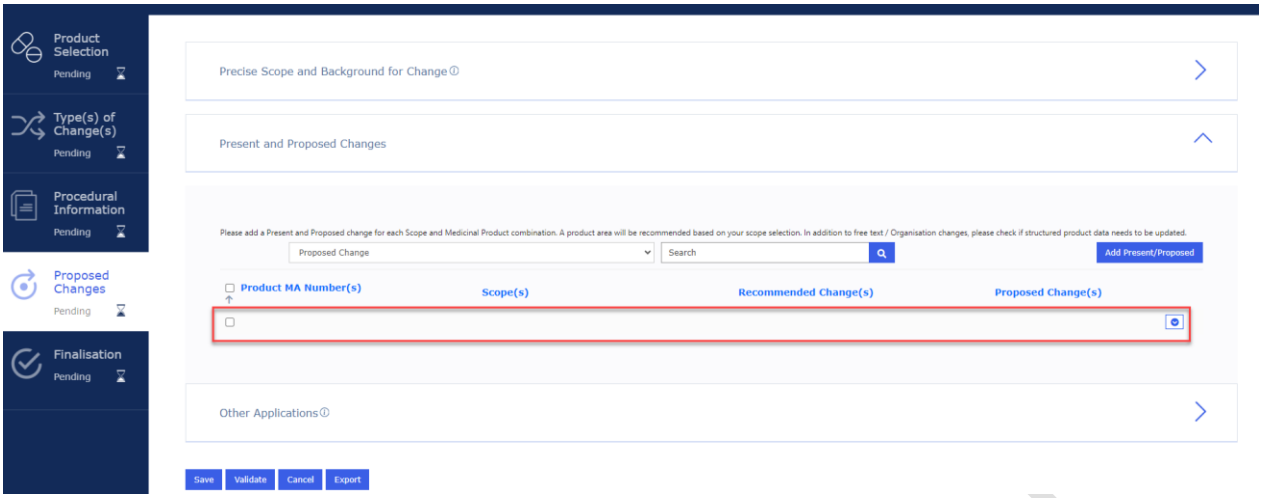


Figure 45 - Proposed Changes

2.5.2.1. Present and Proposed Text Changes

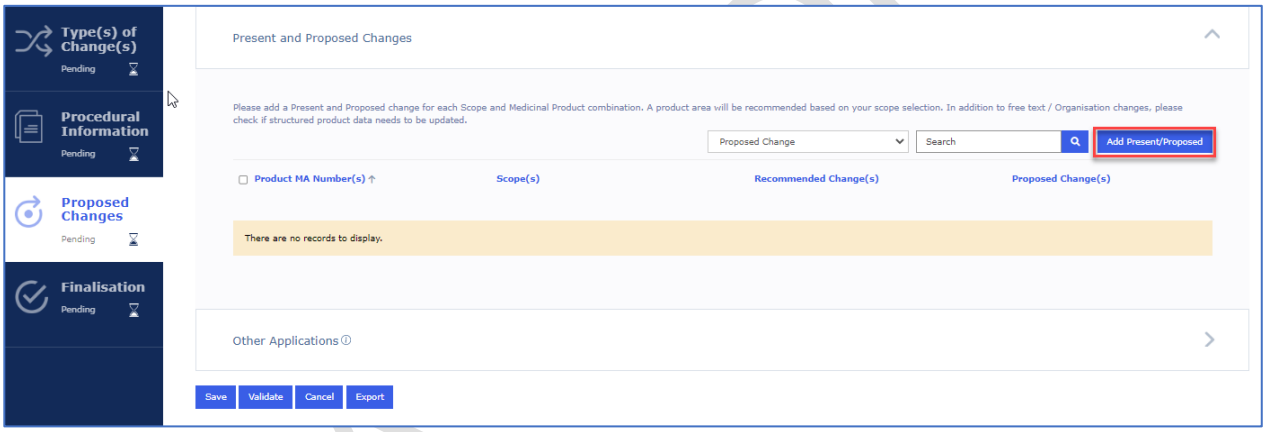


Figure 46 - Present and Proposed Changes

1. Click the Add Present/Proposed button to launch the Present and proposed subsection to add details of the changes and to combine the scope(s) and the presentation(s).

   Note that you are not able to select anything from the Proposed change dropdown menu at this point, you must Add Present/Proposed first to be able to launch this step to add for example Medical Device.

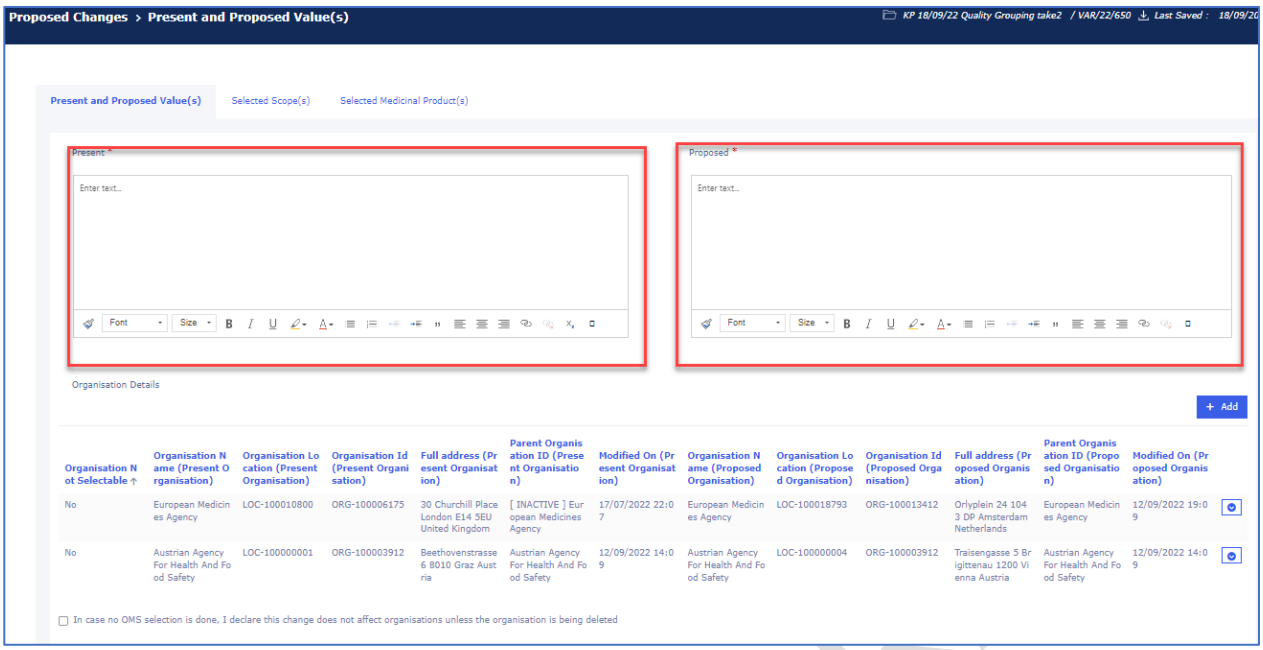


Figure 47 - Present and Proposed Values

Please add the free text changes and images and make use of the editing options. Please note that you may be only able to paste plain text to these fields from another document. Copying edited text (e.g., bold 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).

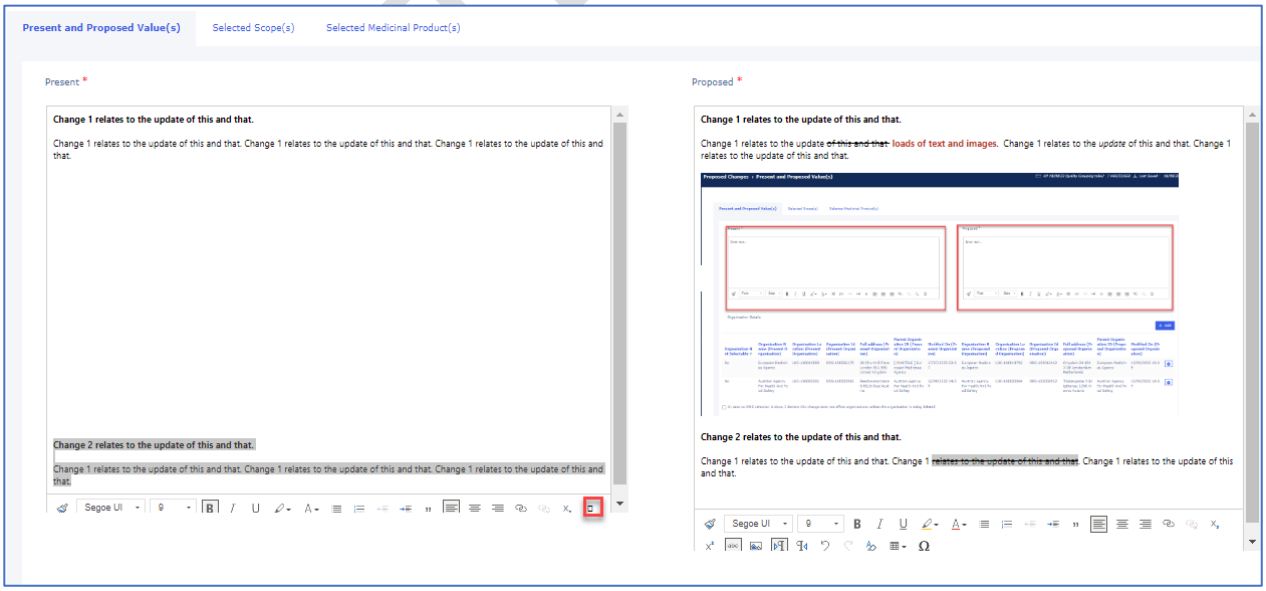


Figure 48 - Present and Proposed Values - Toolbar Options

Please note: There is currently an issue with the design which means that it is not possible to save the changes constantly in this section. In order not to lose any changes, ensure that you either **save**

the free text in the Present and Proposed fields before **selecting the organisations that are impacted from OMS**. Changes added to the Present and Proposed fields **will be lost** if you enter these first and then add an organisation details using the + Add button to select the Present and Proposed organisations without saving.

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

1. Once you have added the editorial changes, relating to a specific scope(s) and packaged medicinal product(s) (i.e. presentation(s) you wish to link to together, please navigate using the tabs at the top of the section to link the scope and product. This is a mandatory step and the **selections of the Packaged Medicinal Products in this section defines which MA numbers are listed in section 2 of pdf** output form.

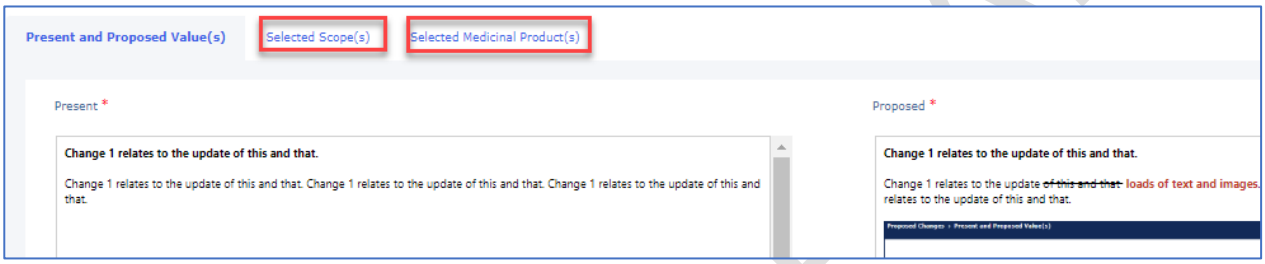


Figure 49 - Selection of Scope and Medicinal Product

2. In the 'Selected Scopes' 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 you selected in the Product selection. If all changes concern all products/presentations, simply select all of them. You can repeat this step to link the changes in present and proposed to a particular scope/product combination.

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

Please note that you **cannot** save the section before selecting at least one scope and one MA number. Note that this section of the input form is likely to be redesigned in future to improve user friendliness and performance.

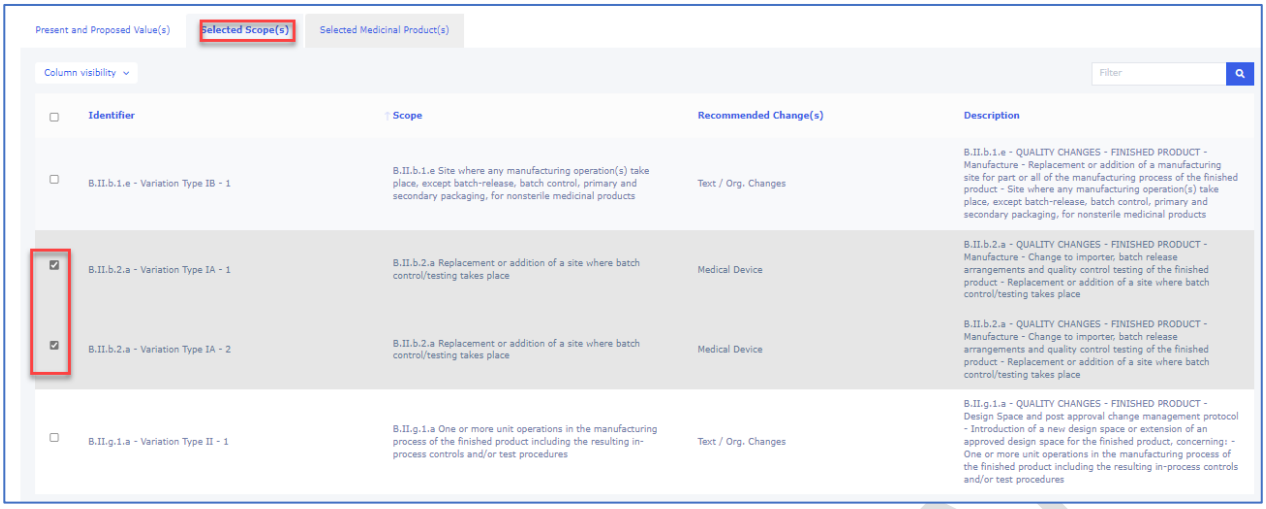


Figure 50 - Selection of Scope and Identifier

3. Select the related Medicinal Product(s)/presentations and click Save to return to the Present and Proposed main menu to add more 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.

NOTE:

There is some inconsistent behaviour in the Selected Medicinal Product screen;

Occasionally, the section to select the Packaged Medicinal Products (the MA numbers) is not populated preventing the selection of the impacted MA numbers. As the system doesn't allow to save without selecting a combination it can be difficult to move forward. If this happens, try to select at least one scope and one medicinal product, and then navigate back to the Present and Proposed value(s) tab and press save in this section.

There is another issue where packages are occasionally auto selected and occasionally not. Occasionally, only some of the packaged medicinal products are selected. Please ensure that you scroll through the list if you cannot see all packages on the screen to ensure that all relevant presentations are selected.

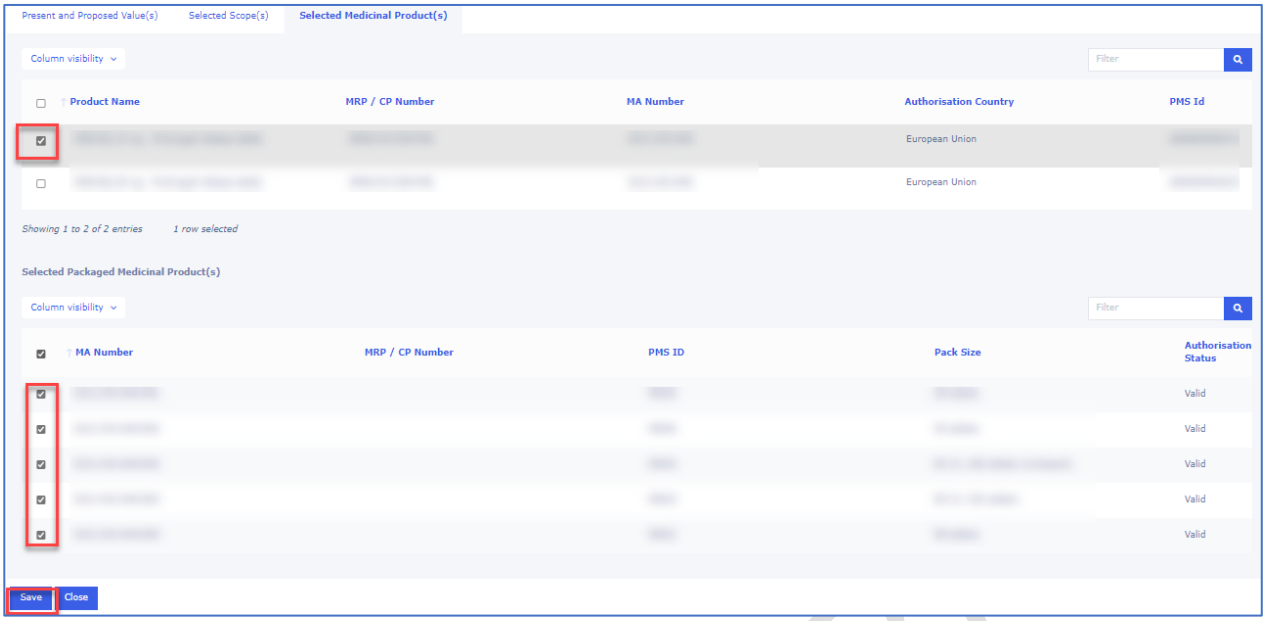


Figure 51 - Selection of Products and MA

4. 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 Present/Proposed. The selected scopes and products will be shown and can be edited

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.

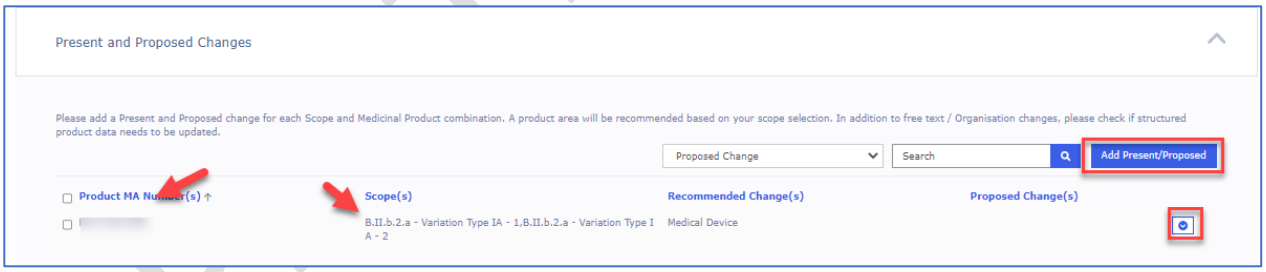


Figure 52 - Add Present/Proposed Changes

2.5.2.3. Organisation Details

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

Please note: There is currently an issue with the design which means that it is not possible to save the changes constantly in this section. In order 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. In the Proposed Changes page– Present and Proposed Value(s) subsection, if you need to add an organisation, please note that it is very important to save the changes done in the free text fields before you **do this step first** in order not to lose any changes, click on + Add button to select the Present and Proposed organisations.

2. 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

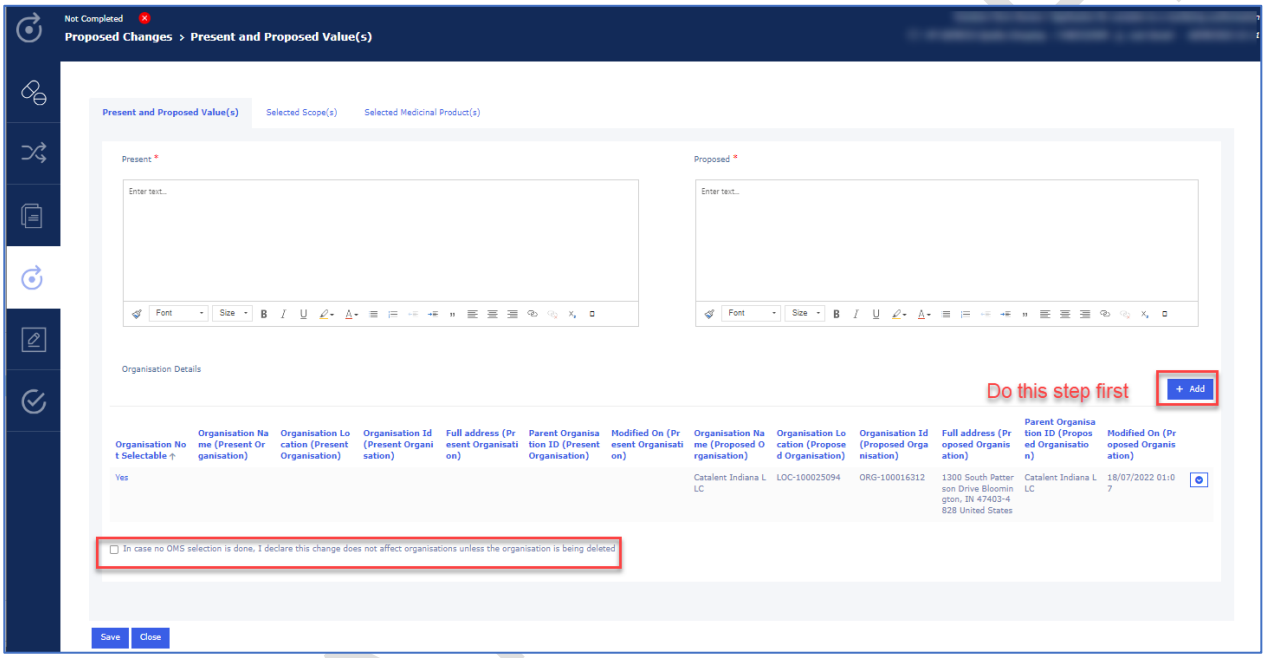


Figure 53 - Present and Proposed Value(s)

3. In the Proposed changes – Present and Proposed Value(s) – Add/Edit organisation subsection, click on the magnifying glass to launch the OMS search to select the Present and Proposed organisations. Please note that there is currently a business rule error which makes the 'present organisation' field mandatory, this is an issue only if you are adding a new organisation.

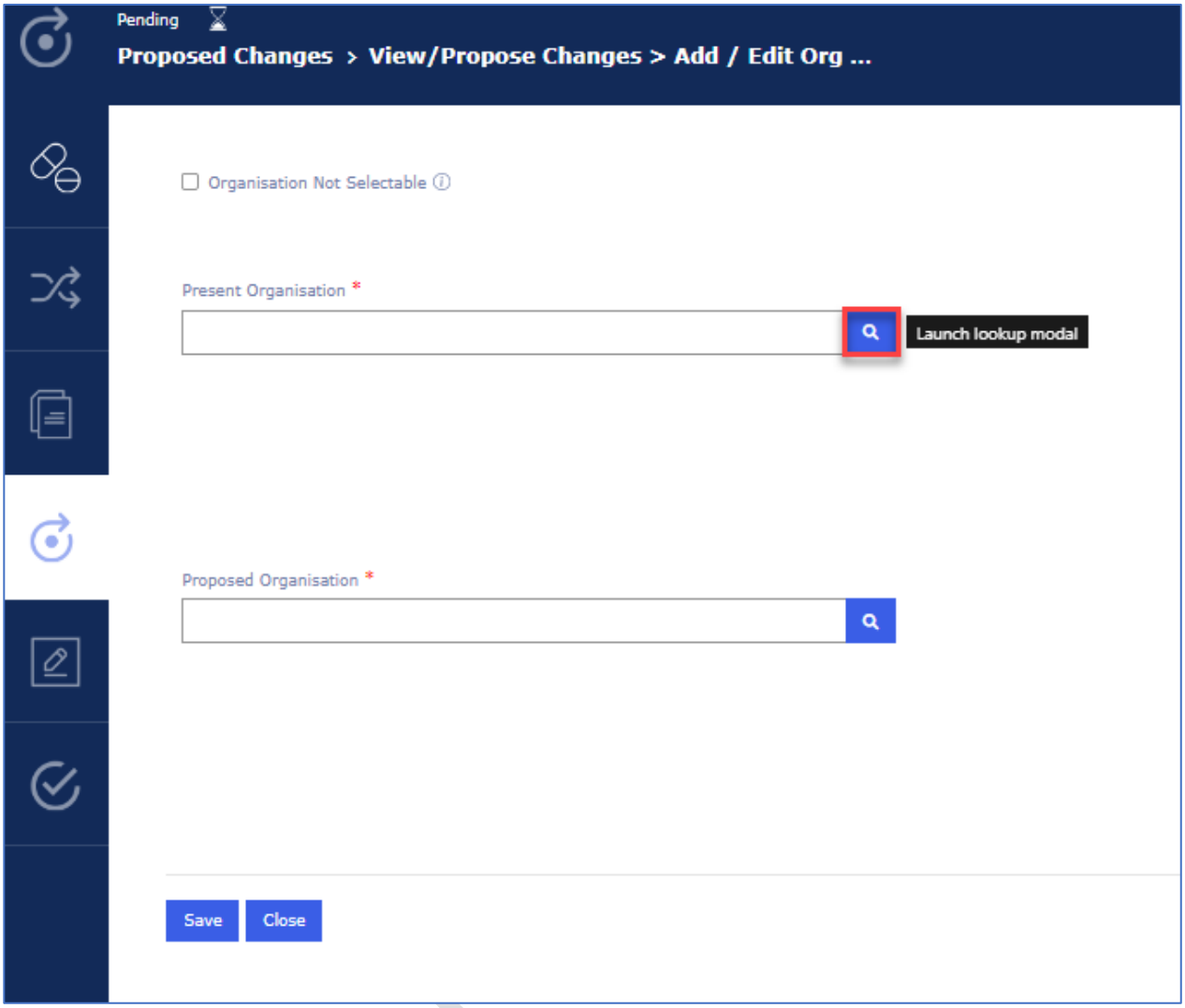


Figure 54 - Proposed Changes - Add/Edit Organisation

4. In the Select Present Organisation, use the search to find the organisation from OMS. You can only select one organisation.

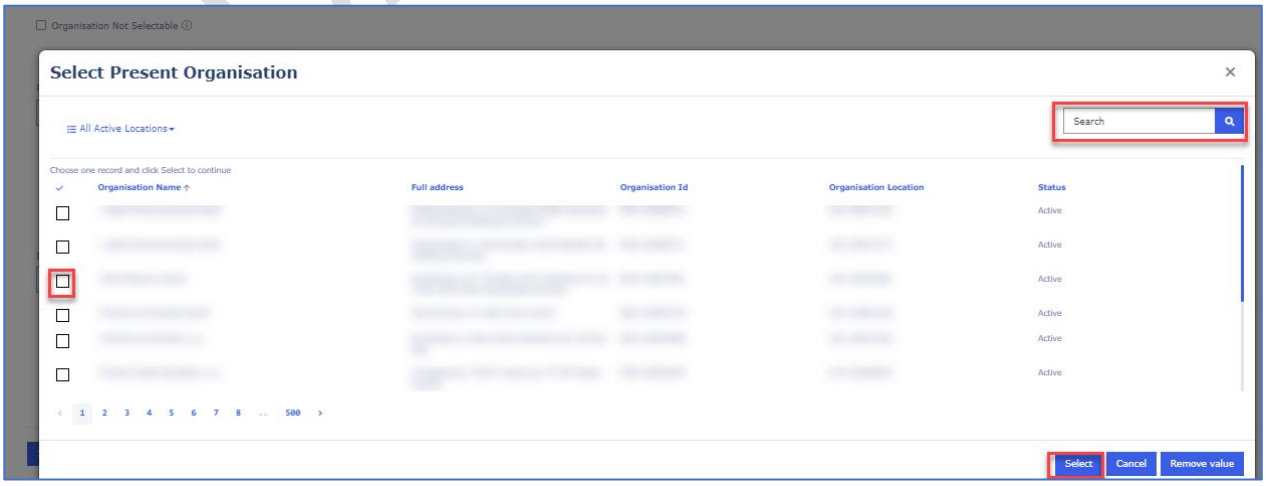


Figure 55 - Select Present Organisation

5. 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 before providing free text address in this field.

Figure 56 - Organisation Not Selectable

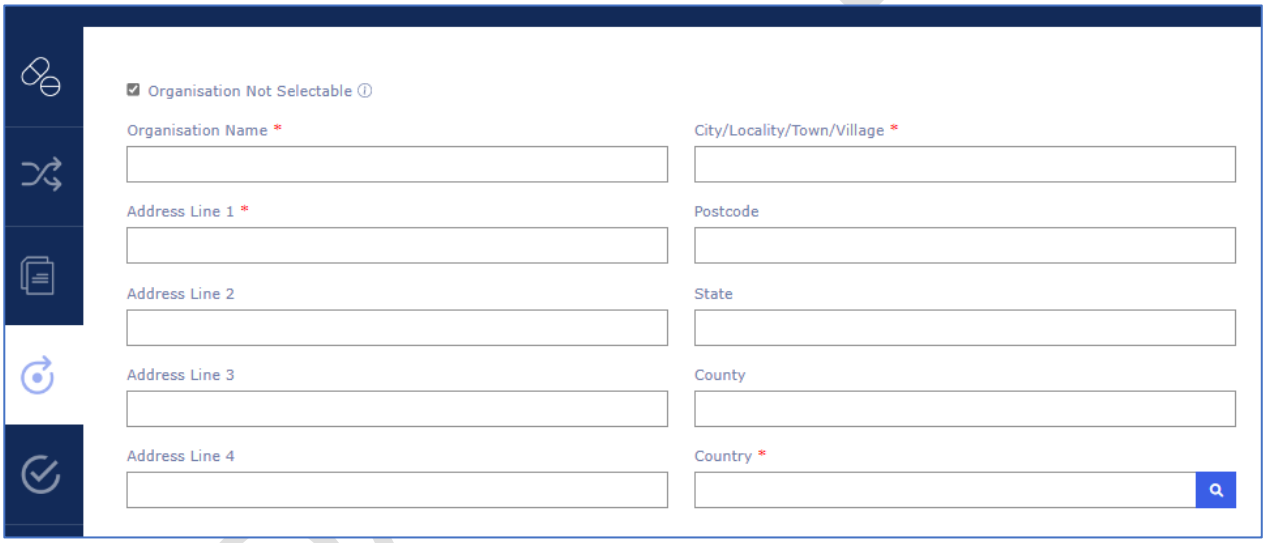


Figure 57 - Data of Not Selectable Organisation

6. Add the details of the present organisation in the free text fields (only if the organisation is not available in OMS.

7. 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.

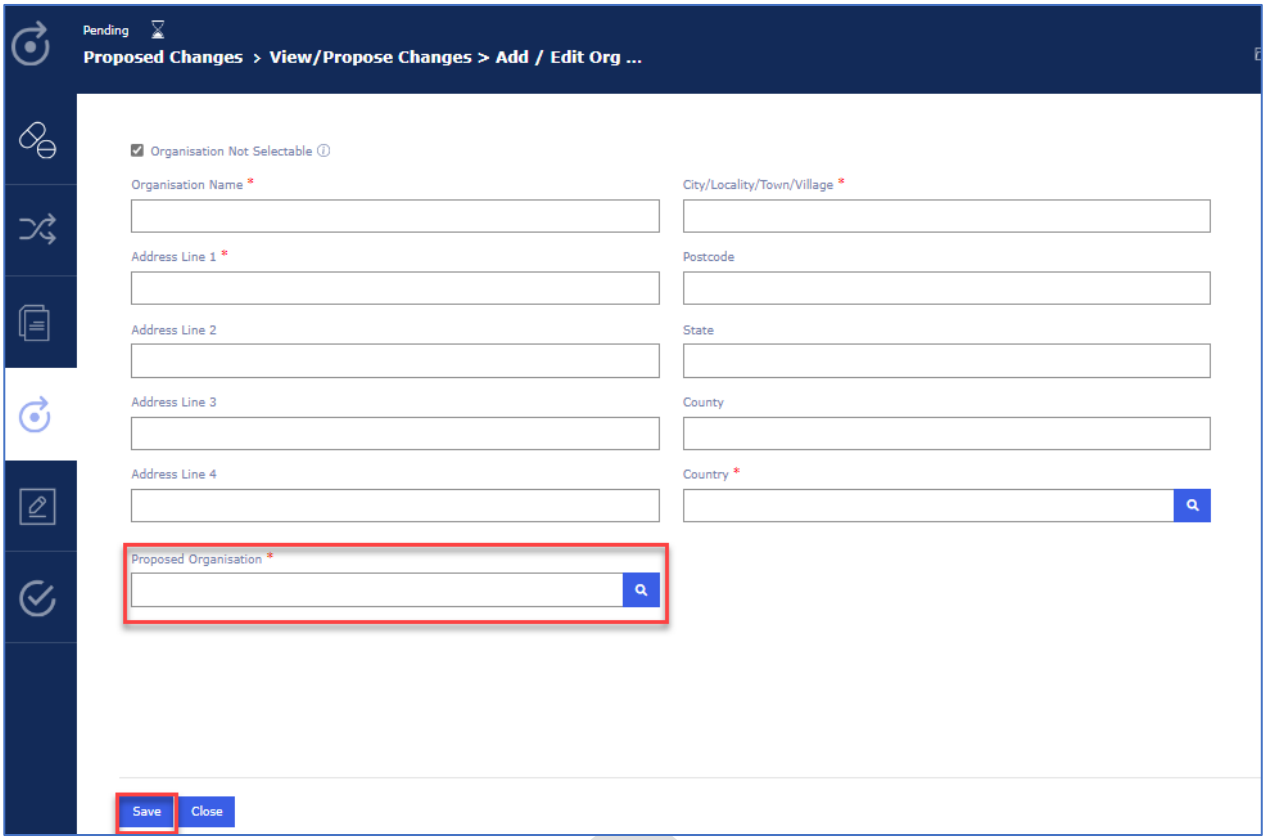


Figure 58 - Proposed Organisation

8. Select the organisation and press on the Select button.
9. When both organisations have been added, press the Save button to return to the Present and Proposed section to add the textual changes.

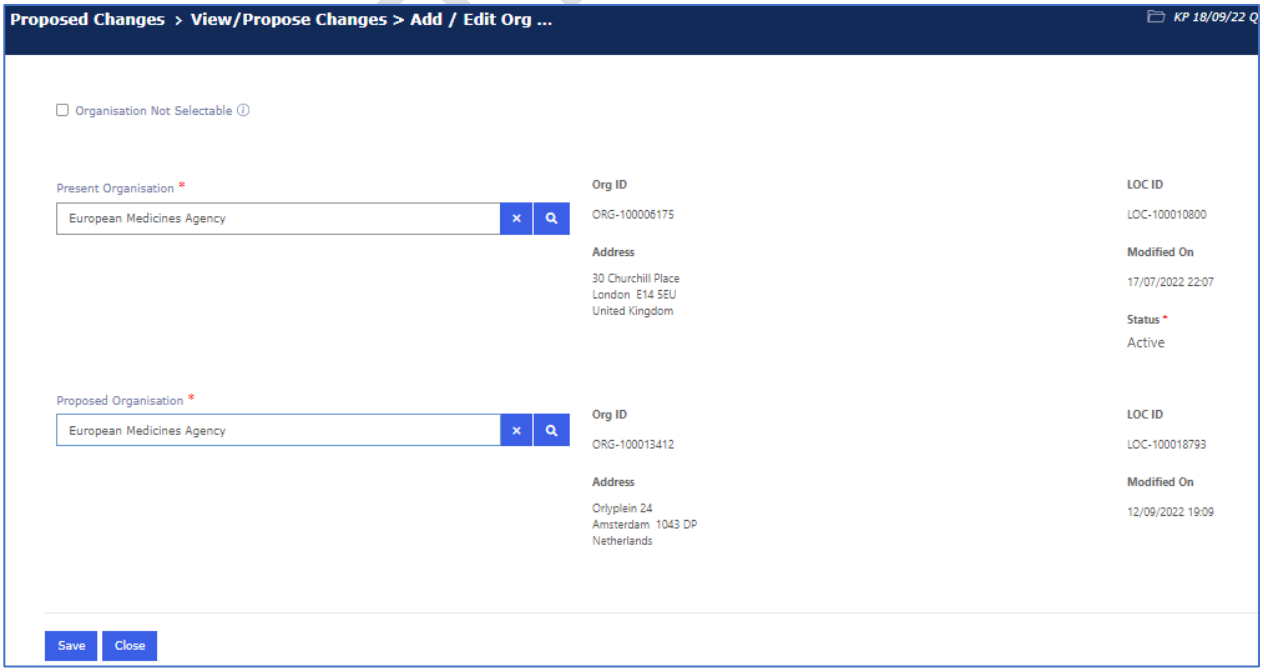


Figure 59 - Present and Proposed Section

10. 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.

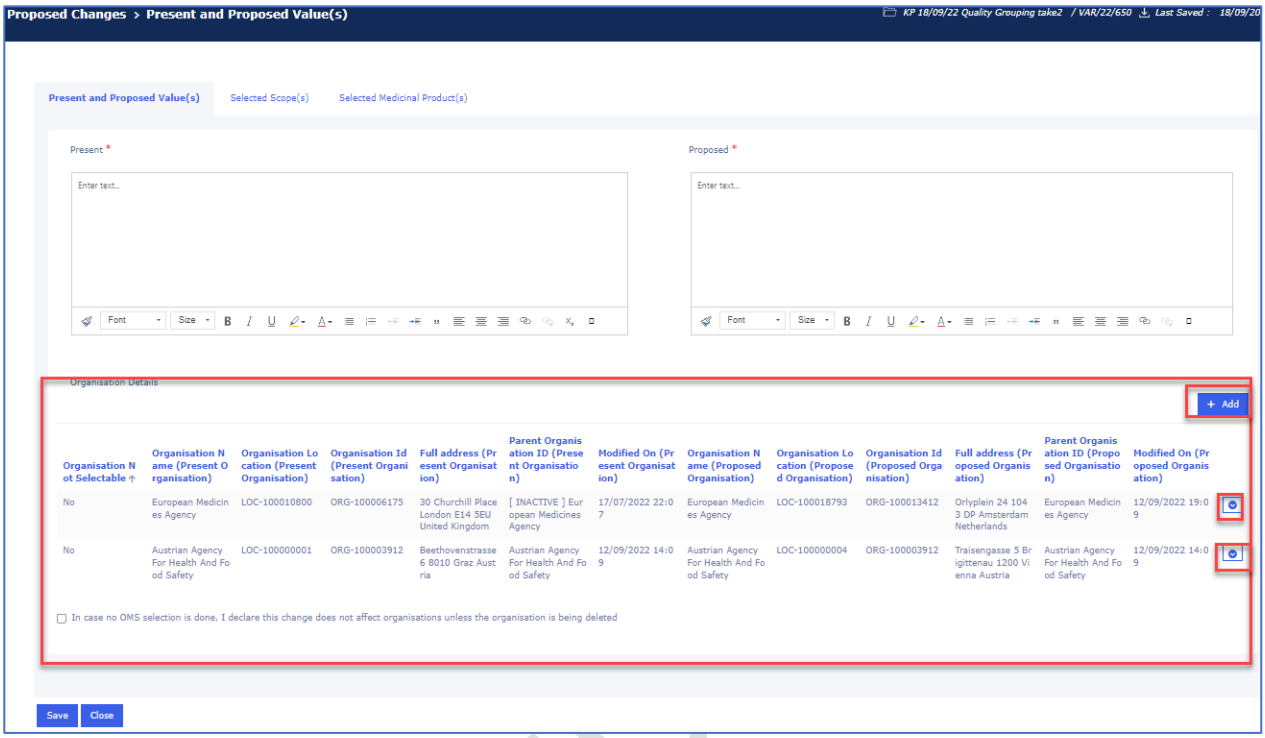


Figure 60 - Present and Proposed Value(s)

Please note that you can view the manually entered organisation details in the present and proposed section of the web form. These details are only shown when the user clicks the 'Yes' link in the UI. This launches a pop-up window where the manually entered details are visible.

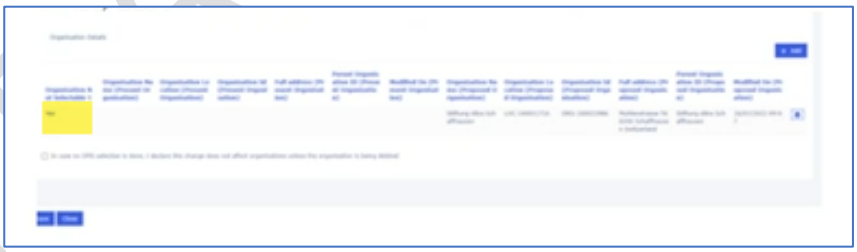
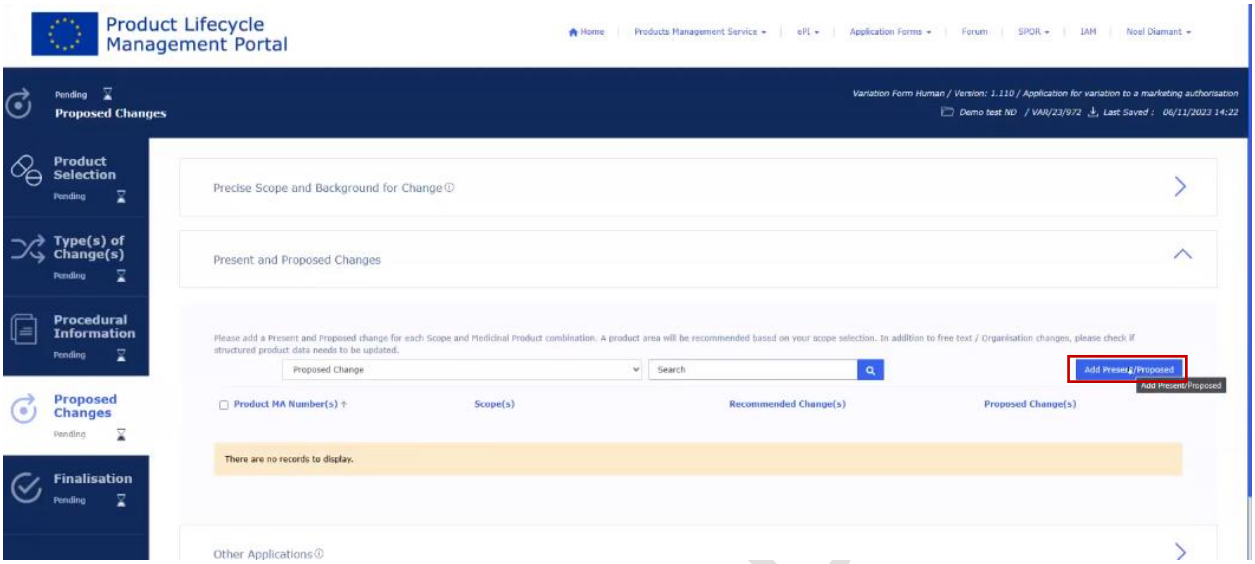


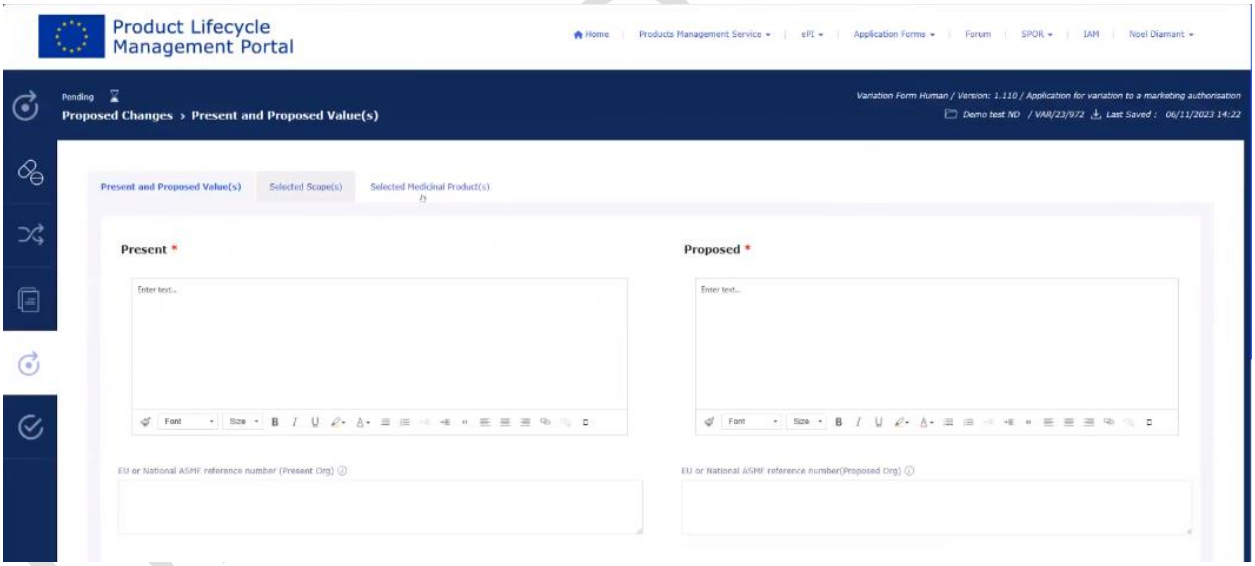
Figure 61 - Pop-Up showing details inserted

2.5.3.Add Package to an Existing Product – Expected in late Q2 2024

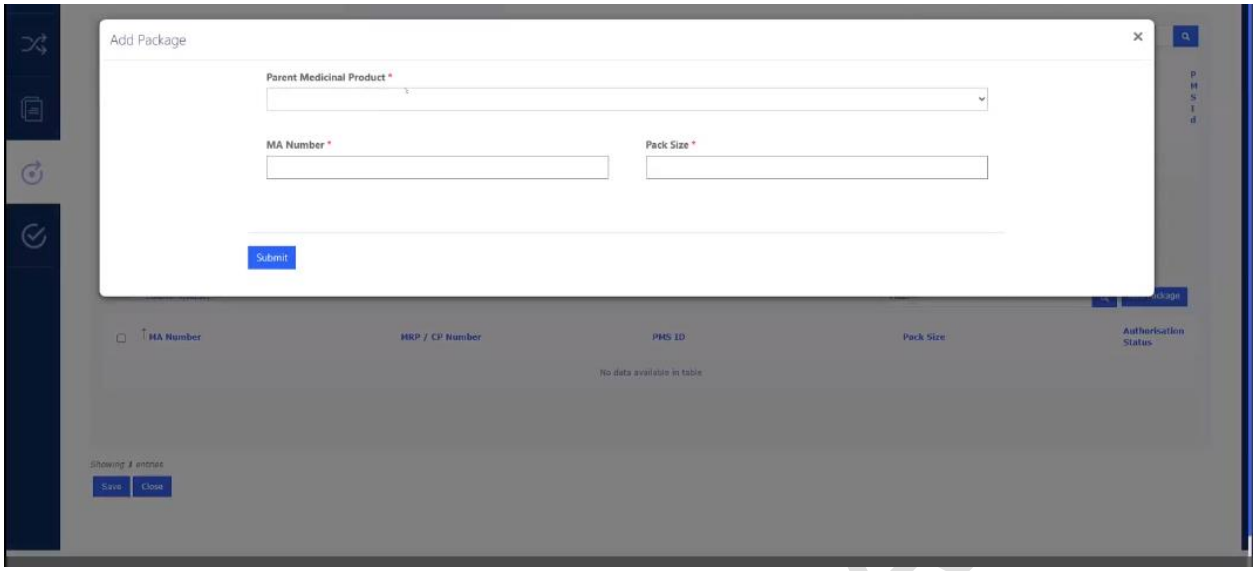
- In order to add a package to an existing product, navigate to the "Proposed Changes" section, then choose "Present and Proposed Changes."
- Subsequently, click on "Add Present/Proposed" to proceed with this action.

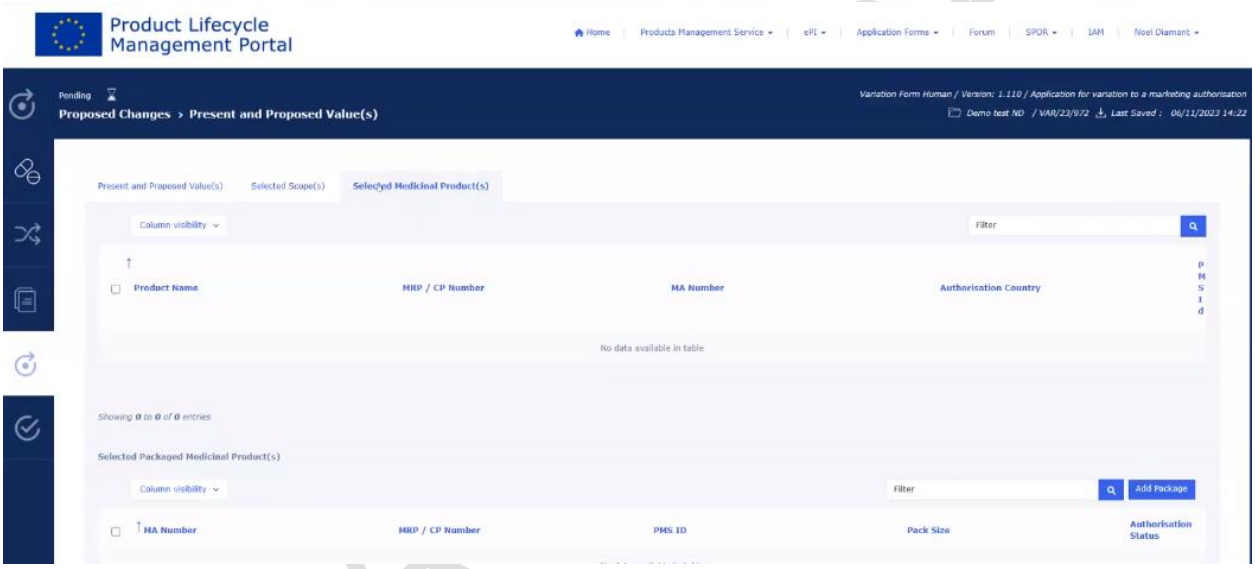


- Select the tab "Selected Medicinal Product(s)."



- In case there is a product listed, you will find the option "add package" available for selection.

- 



- Choose the specific product you desire, input the MA (Marketing Authorisation) number, specify the pack size, and the item will be successfully added to your list.

2.5.3.1. Multiple change

2.5.3.1.1. 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.

2.5.3.1.2. 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.

2.5.3.2. 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.

2.5.3.3. 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.

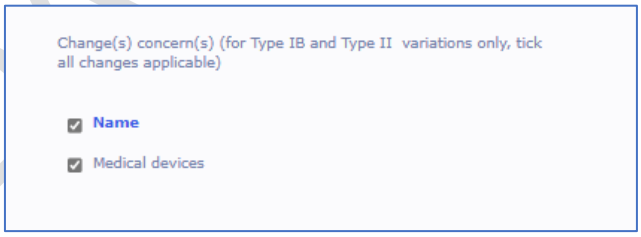


Figure 62 - Medical Device Box

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

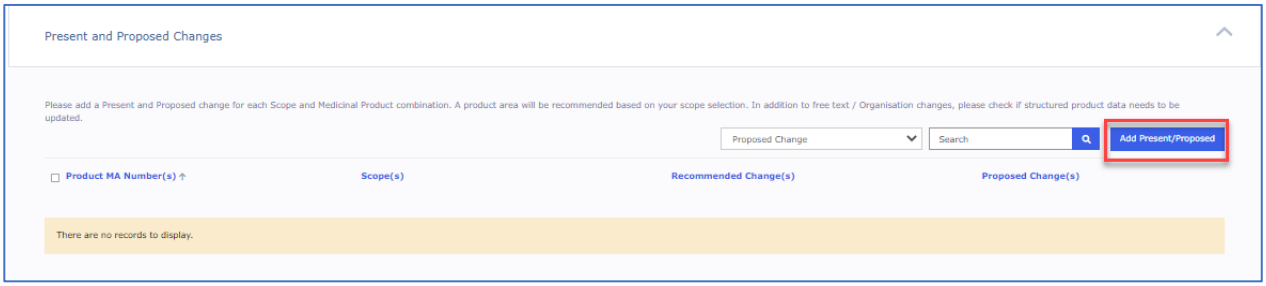


Figure 63 - Add Present/Proposed Changes

3. Select the scope and the medicinal product/presentations

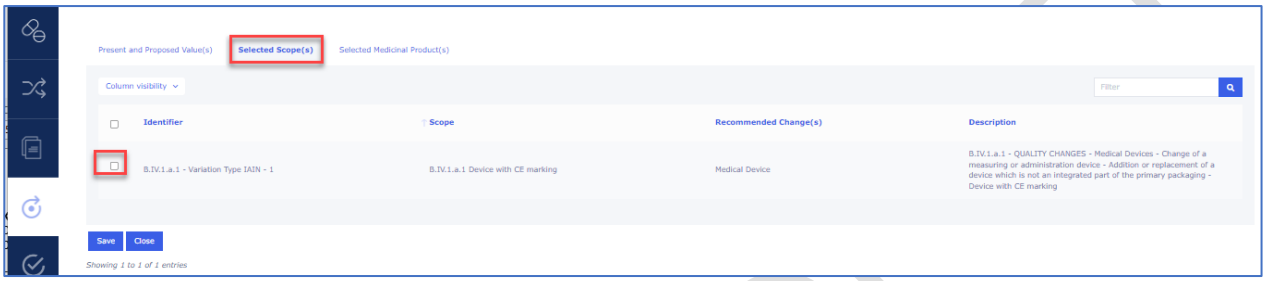


Figure 64 - Selected Scope(s)

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**.

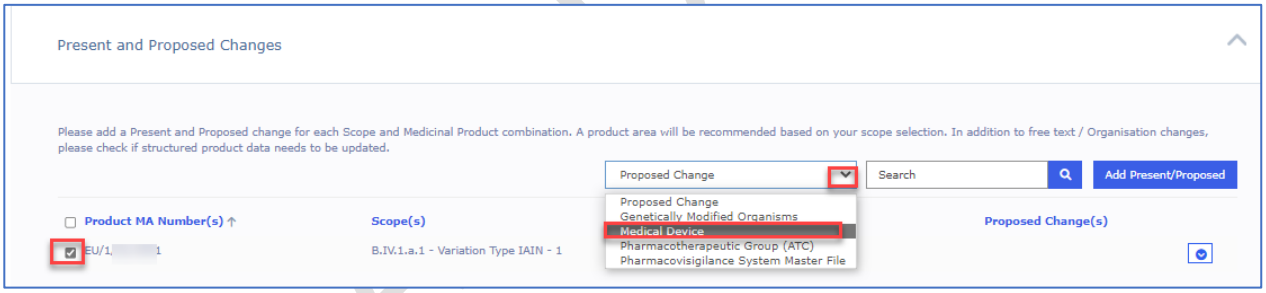


Figure 65 - Selection of relevant scope/product combination

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 (for now). To edit the section click Add Device and you will be able to make the selections as usual in this section.

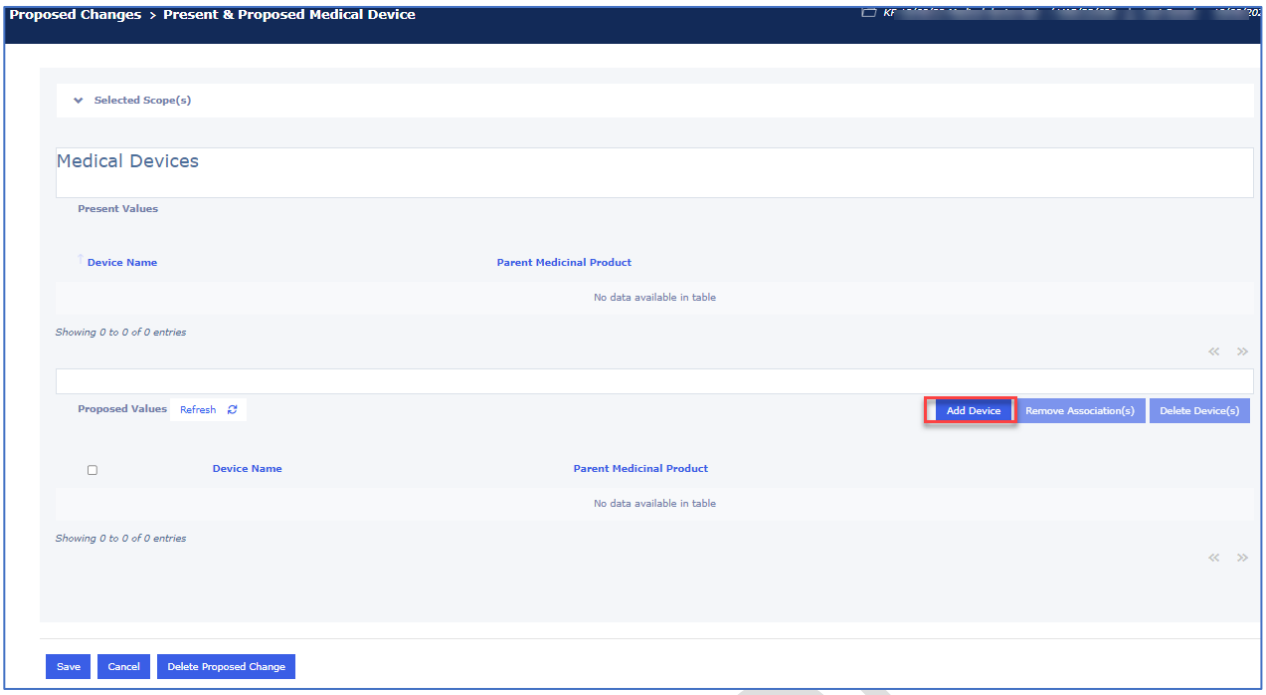


Figure 66 - Add Device

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 67 - Medical Device and Companion Diagnostic

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

Figure 68 - Change Selection - Medical Device and Companion Diagnostic

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

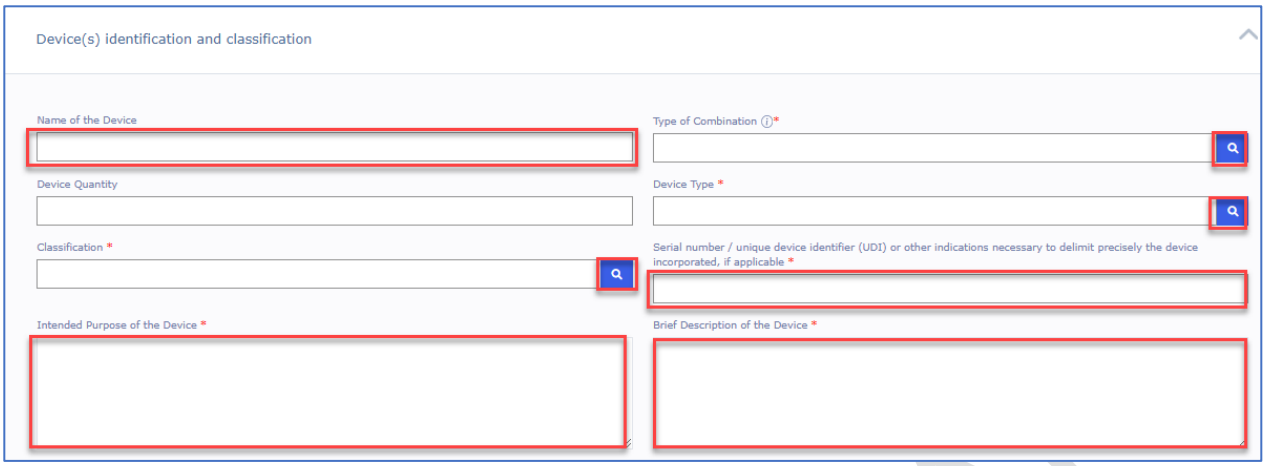


Figure 69 - Device(s) Identification and Classification

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

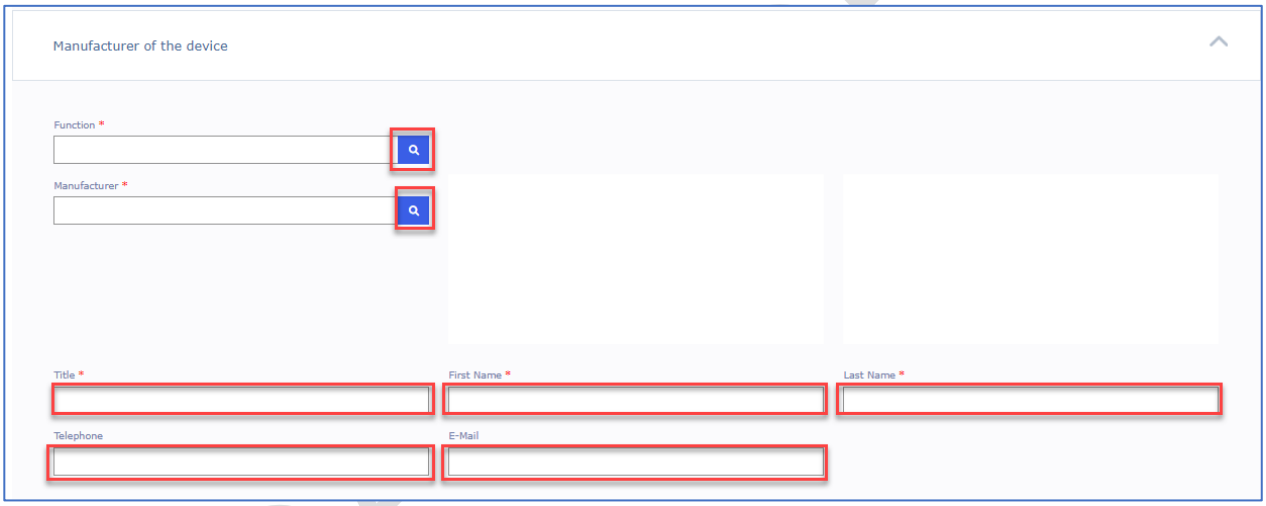


Figure 70 - Manufacturer of the Device

10. Proceed to fill in the rest of the sections

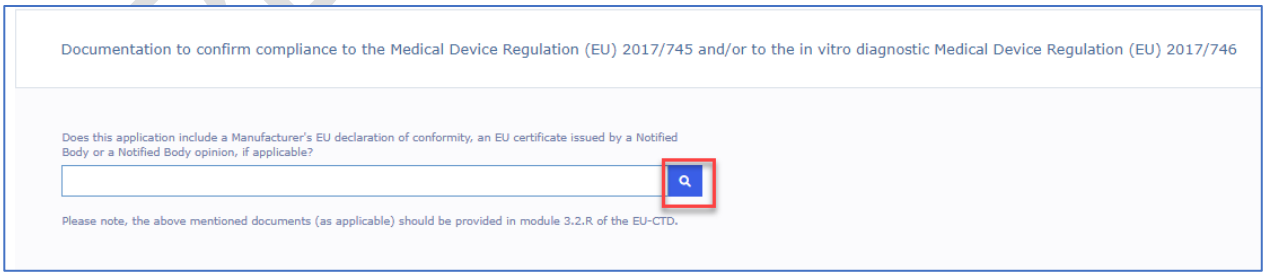


Figure 71 - Upload of Documentation

11. Notified body is also now selected from OMS

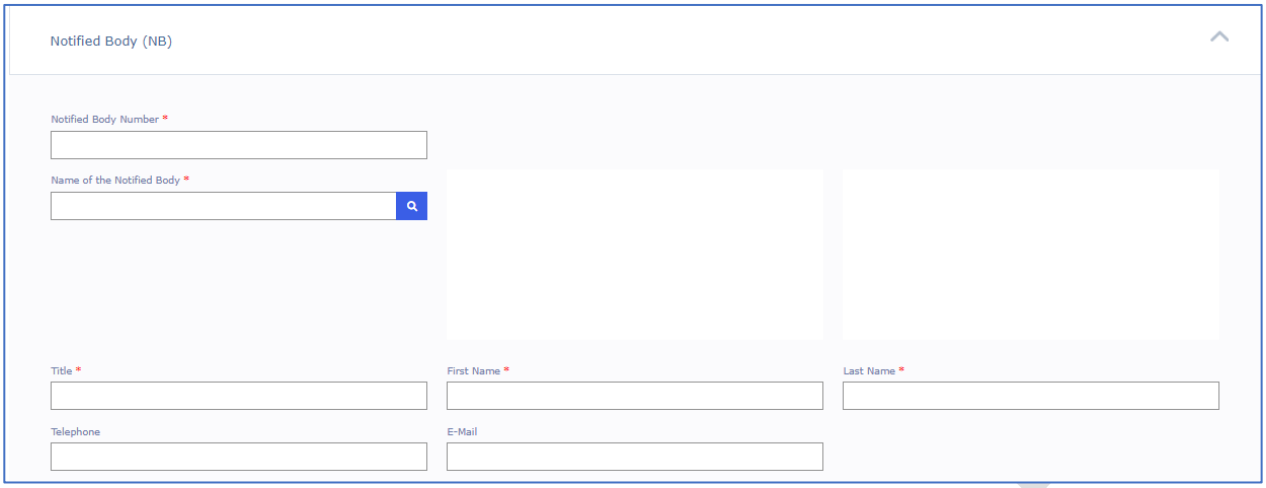


Figure 72 - Notified Body

12. dsd

2.5.3.4. 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**.

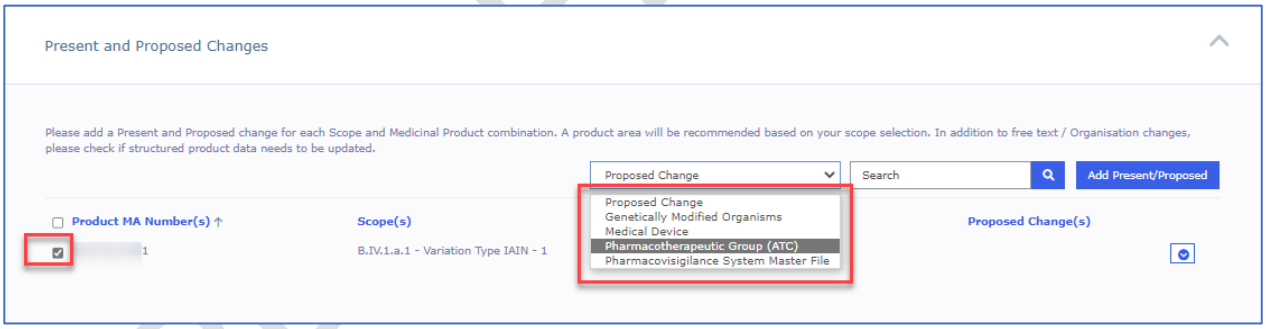


Figure 73 - Present and Proposed Changes

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

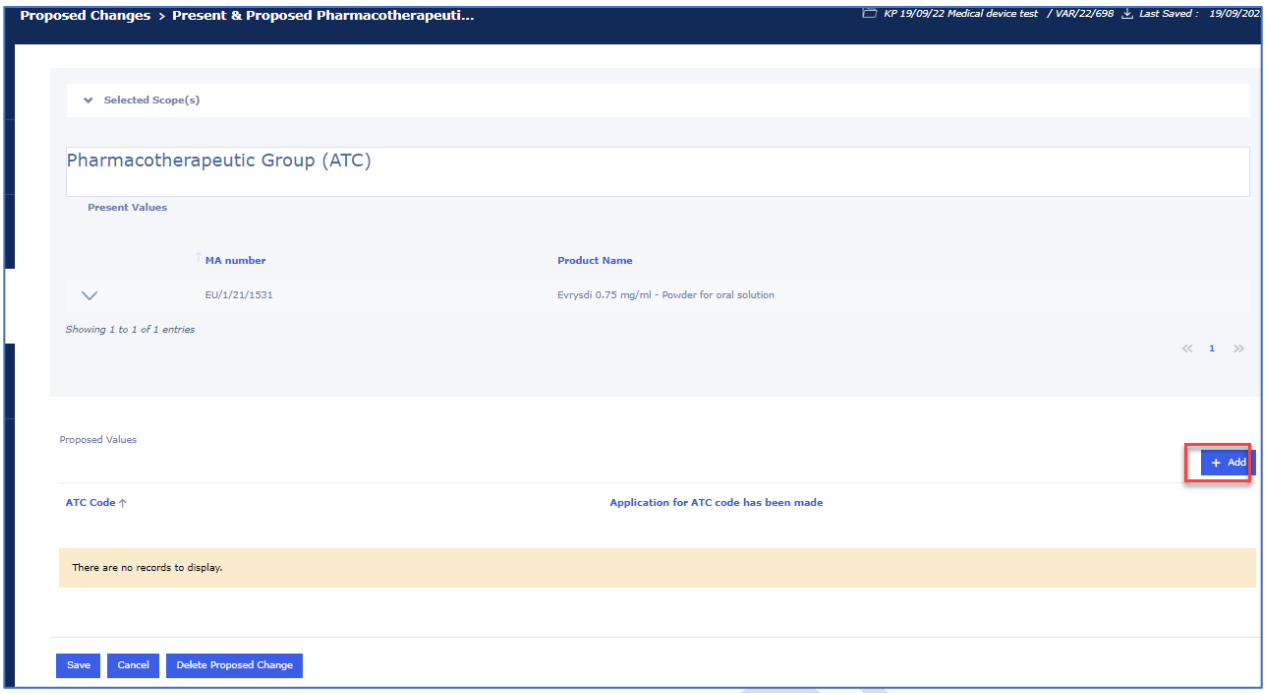


Figure 74 - ACT Code Change

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

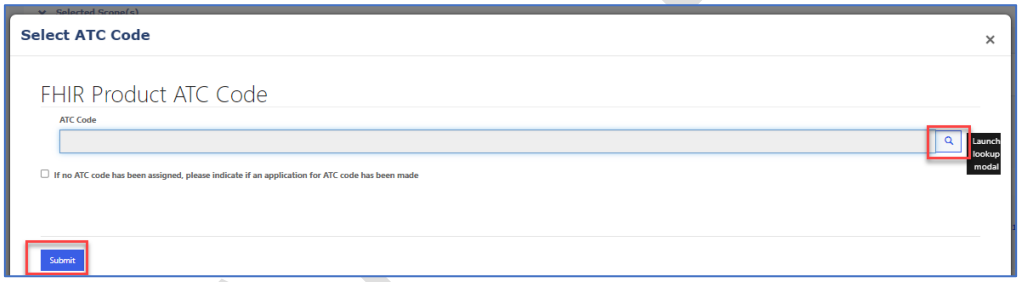


Figure 75 - Selection of ATC Code

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

2.5.3.5. 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.

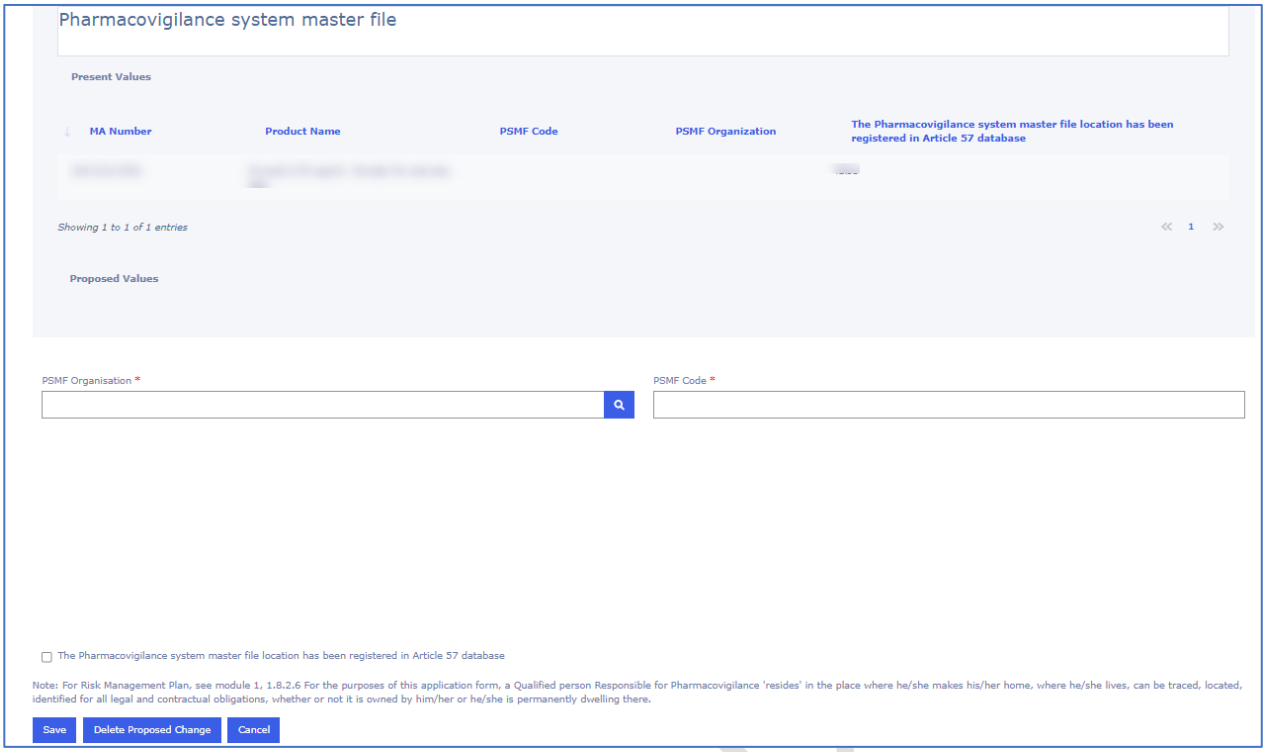


Figure 76 - Pharmacovigilance System Master File

Add the PSMF Organisation from the magnifying glass and the PSMF Code

Click on the Save button and you will be taken back to the Proposed Changes main page

Click on the Save button to save your changes in the form

2.5.3.6. 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.

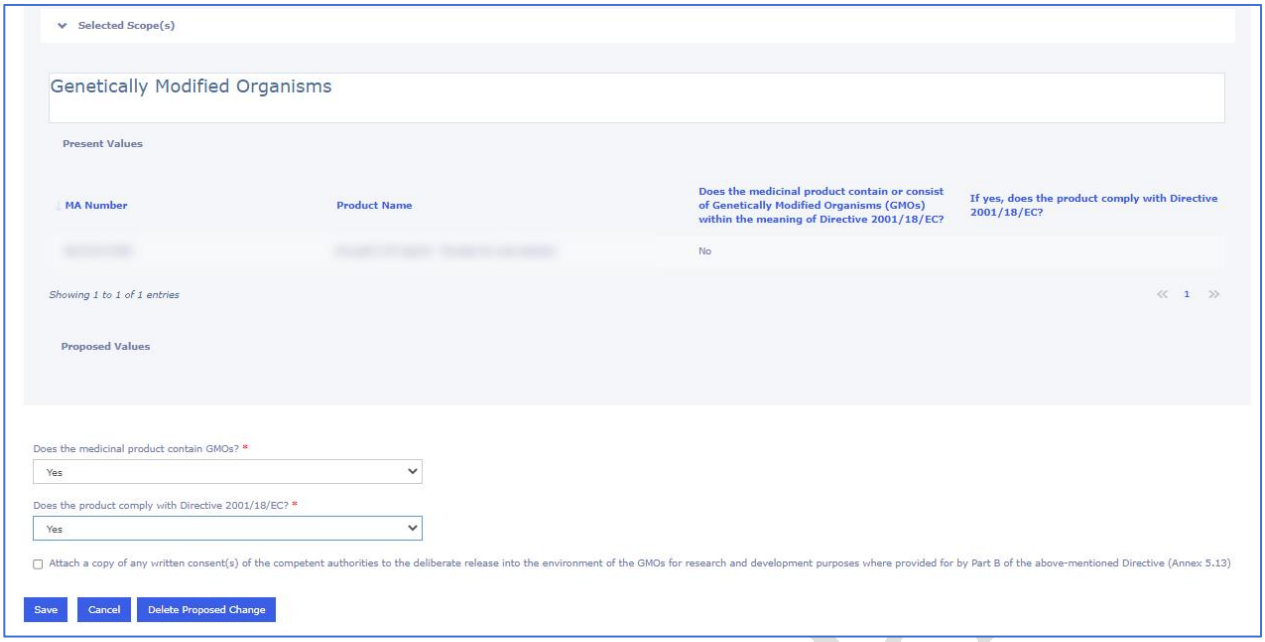


Figure 77 - Genetically Modified Organisms Code

2. Reply to the GMO-related enquiries

Click on the Save button and you will be taken back to the Proposed Changes main page

Click on the Save button to save your changes in the form

2.5.4. 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 enterd 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. If the procedure you wish to add is not available, please use the free text field opened by clicking the Add button

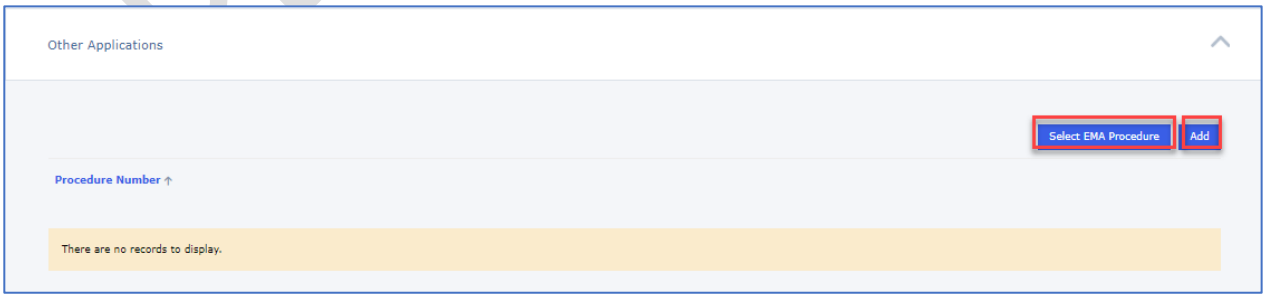


Figure 78 - Selection of EMA Procedure

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 79 - Additional Information Section

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

1. To fill in this section select the relevant orphan designation using the magnifying glass

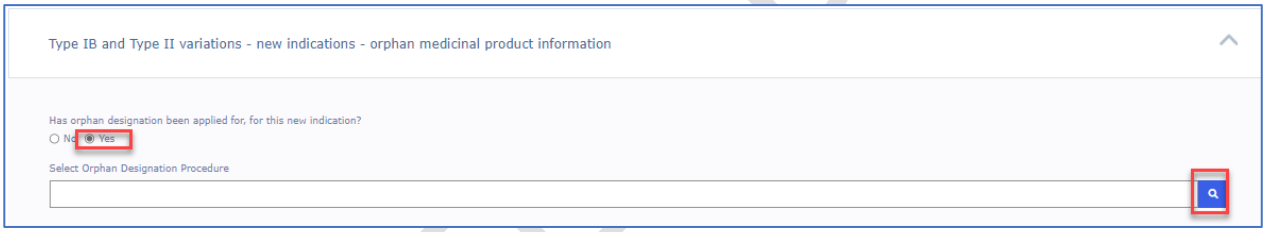


Figure 80 - Orphan Designation Procedure

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

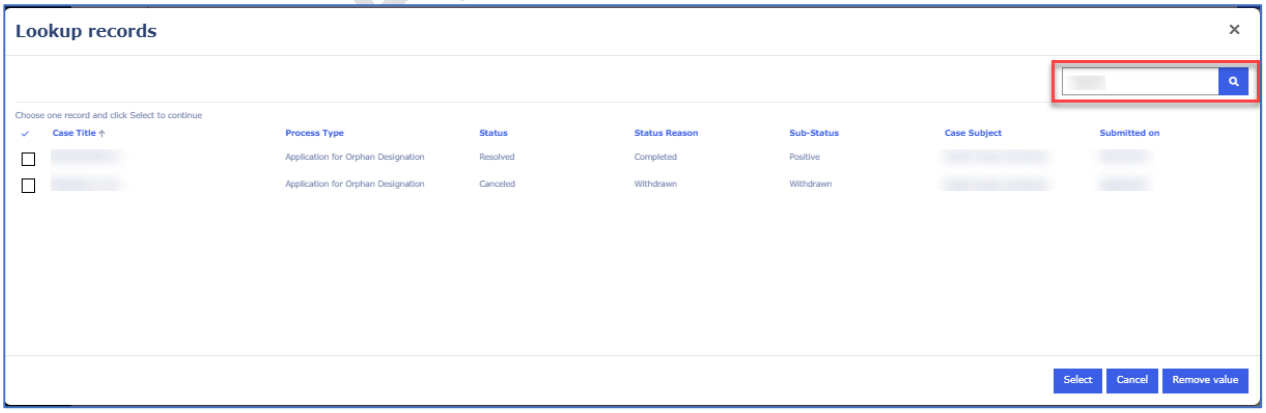


Figure 81 - Lookup Records

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

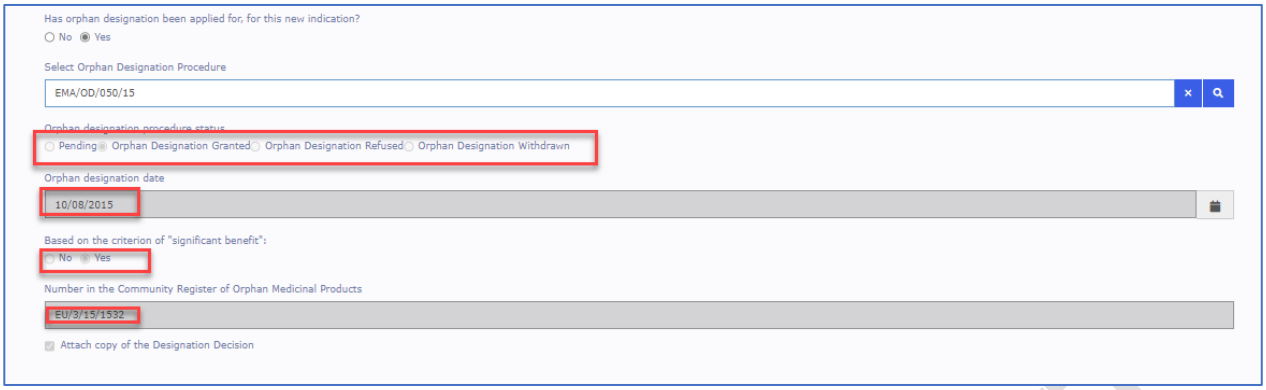


Figure 82 - Selection of Procedure

2.6.2. Information relating to orphan market exclusivity

2.6.3. Type IB and Type II Variations – Paediatric Requirements

The display order and format of the options doesn't correspond to the list order/function in the interactive pdf, but the PDF export will reflect this correctly

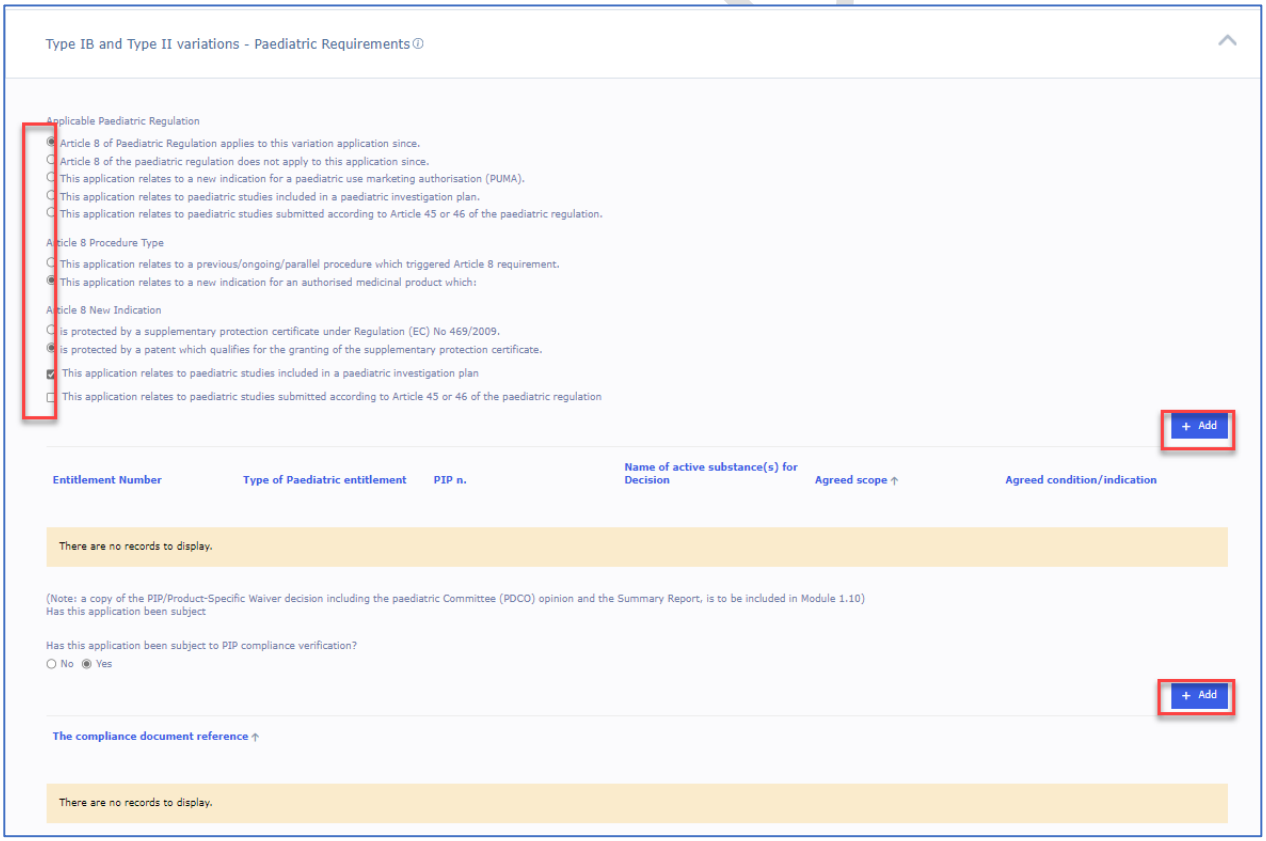


Figure 83 - Type IB and Type II Variations – Paediatric Requirements

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

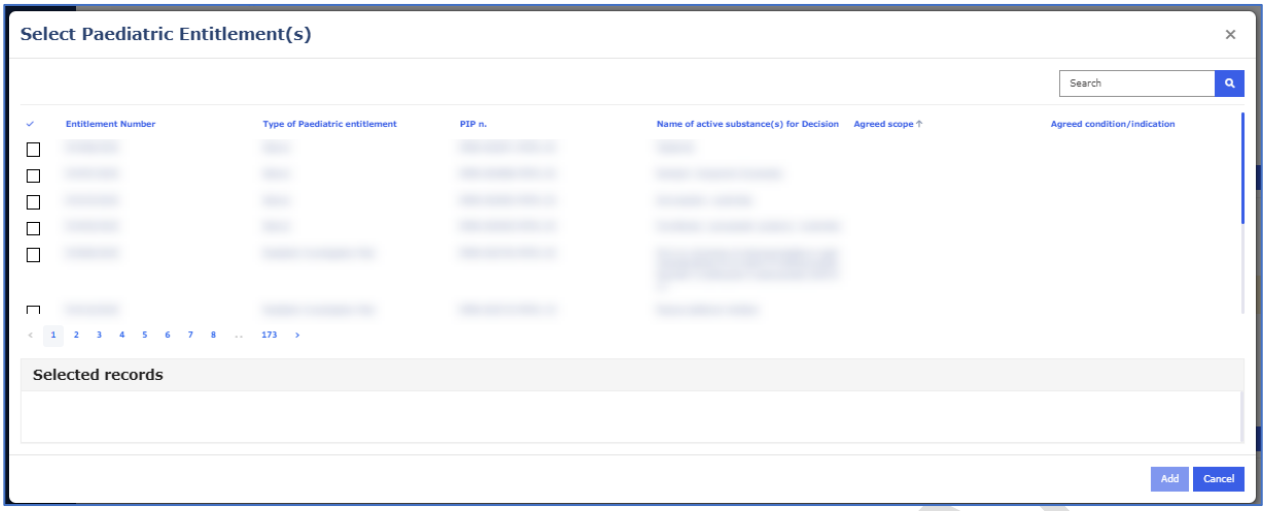


Figure 84 - Selection of Paediatric Entitlement(s)

2. Add the entitlement

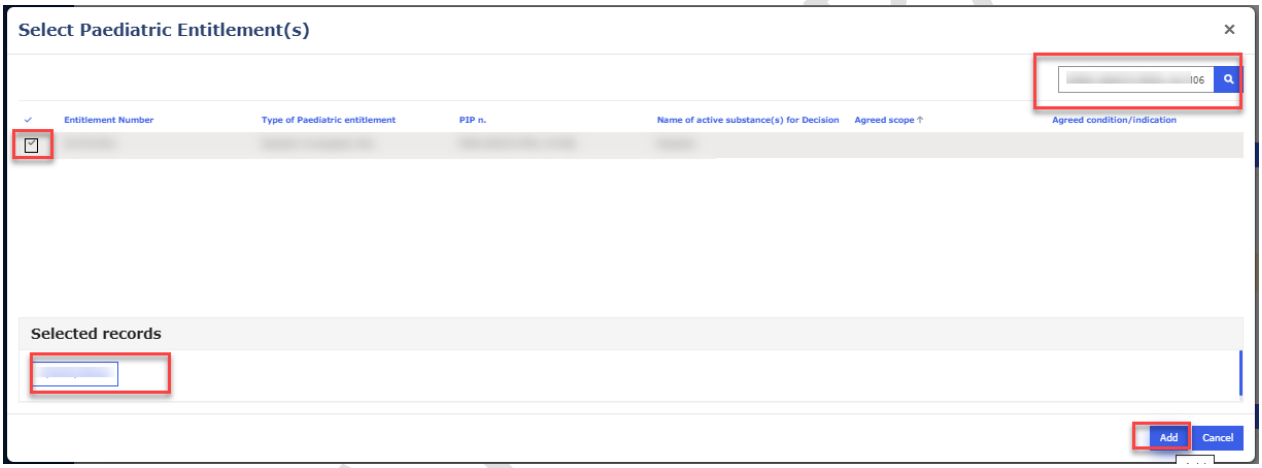


Figure 85 - Addition of Paediatric Entitlement(s)

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

Figure 86 - 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;

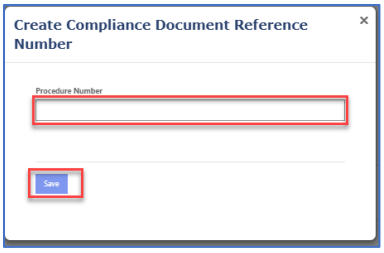


Figure 87 - Creation of Compliance Document Reference Number

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

Figure 88 - Type II Variations – Extended data exclusivity/market protection

2.7. Finalisation

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).

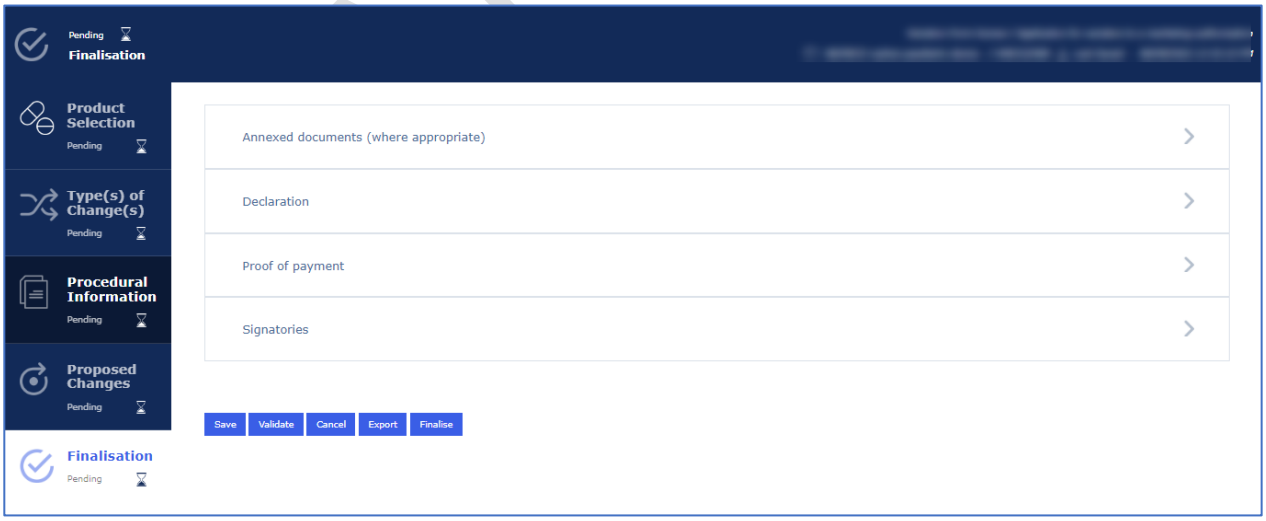


Figure 89 - Finalisation Process

2.7.1. Annexed documents (where appropriate)

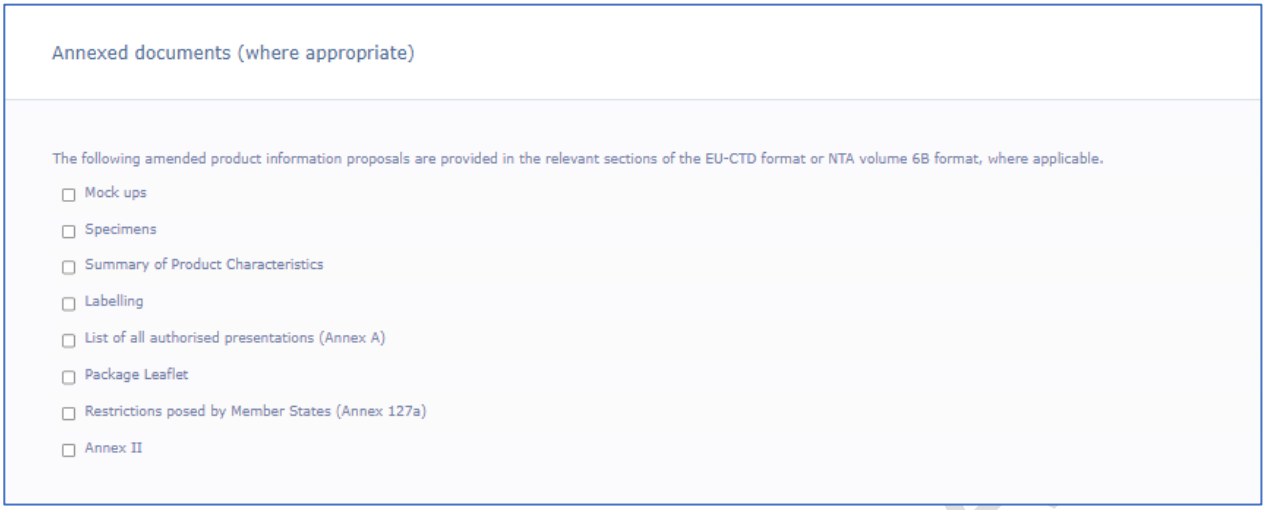


Figure 90 - Annexed Documents

2.7.2. Declaration of the applicant

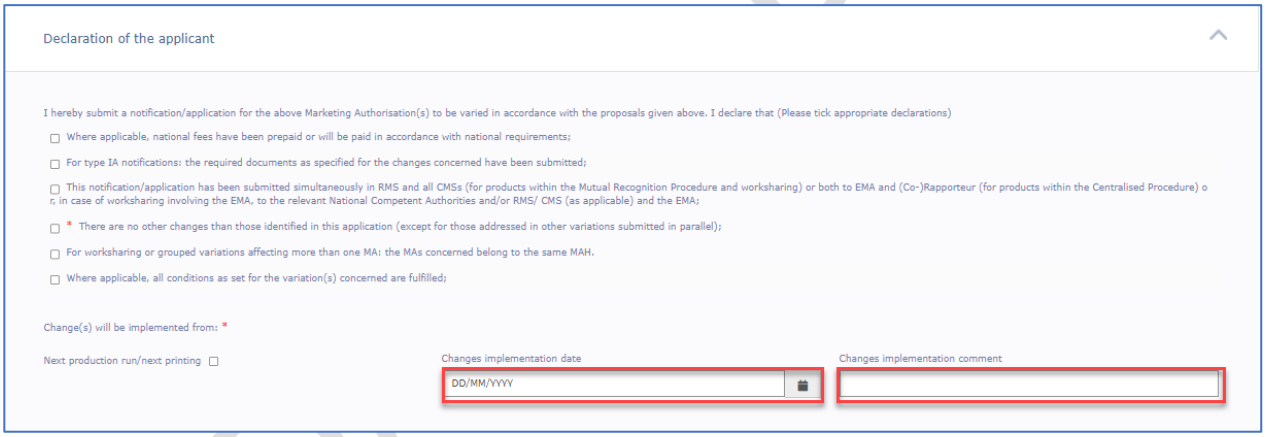


Figure 91 - Declaration of the Applicant

2.7.3. Proof of Payment

For Centralised Procedure applications the Proof of Payment section is defaulted to 'No'

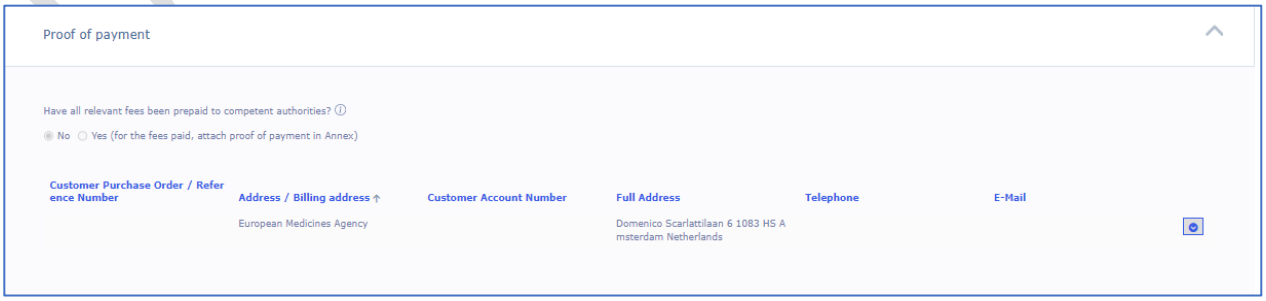


Figure 92 - Proof of Payment

2.7.4. Signatories

Figure 93 - 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 any external signature tool, for example Adobe signature or a more formal digital signature tool. An image of a signature can also be included in the exported pdf if preferred.

3. Exporting the form content to a PDF

3.1. *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

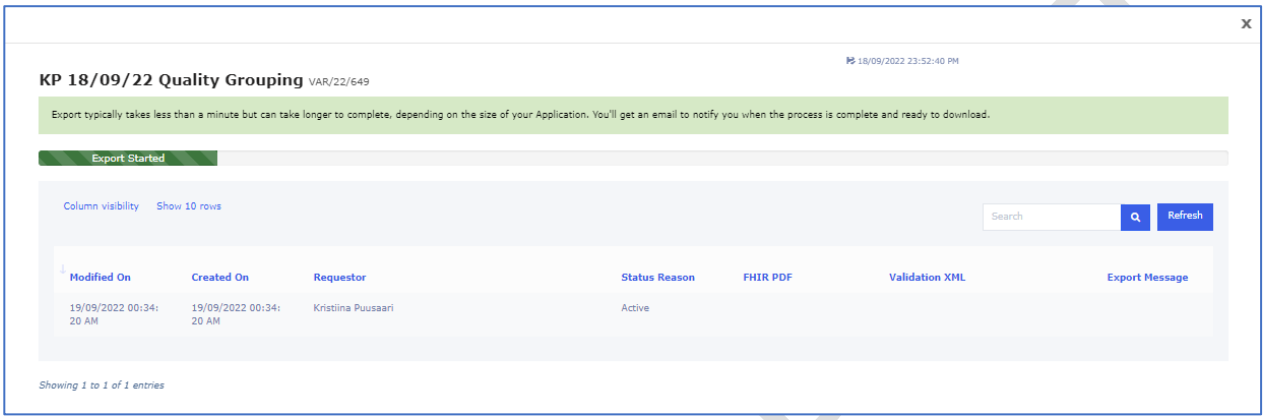


Figure 94 - Preparation of Export

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

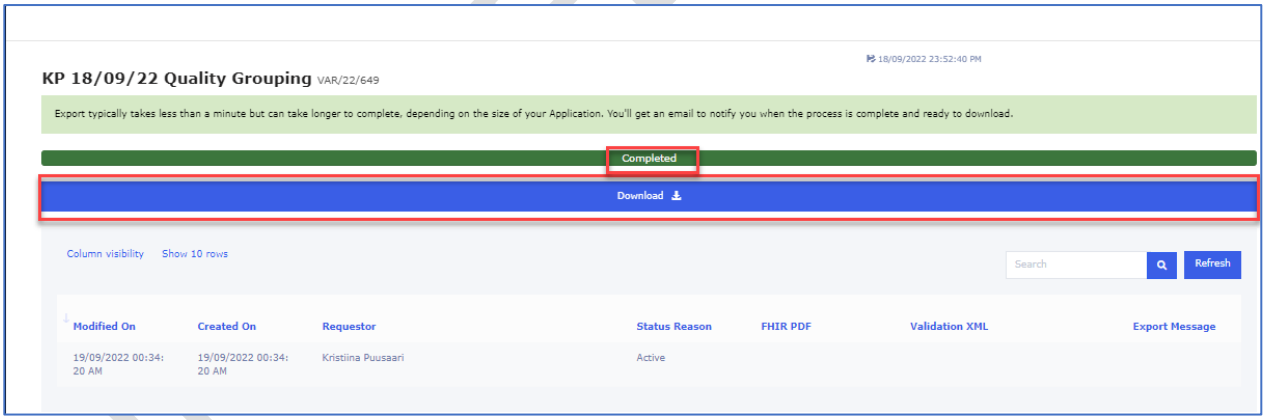


Figure 95 - Export Completed

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.

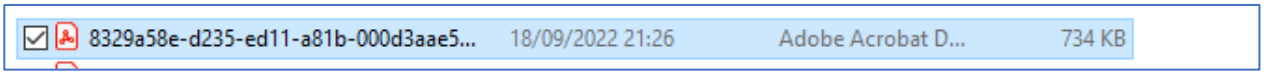


Figure 96 - Exported Form

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.

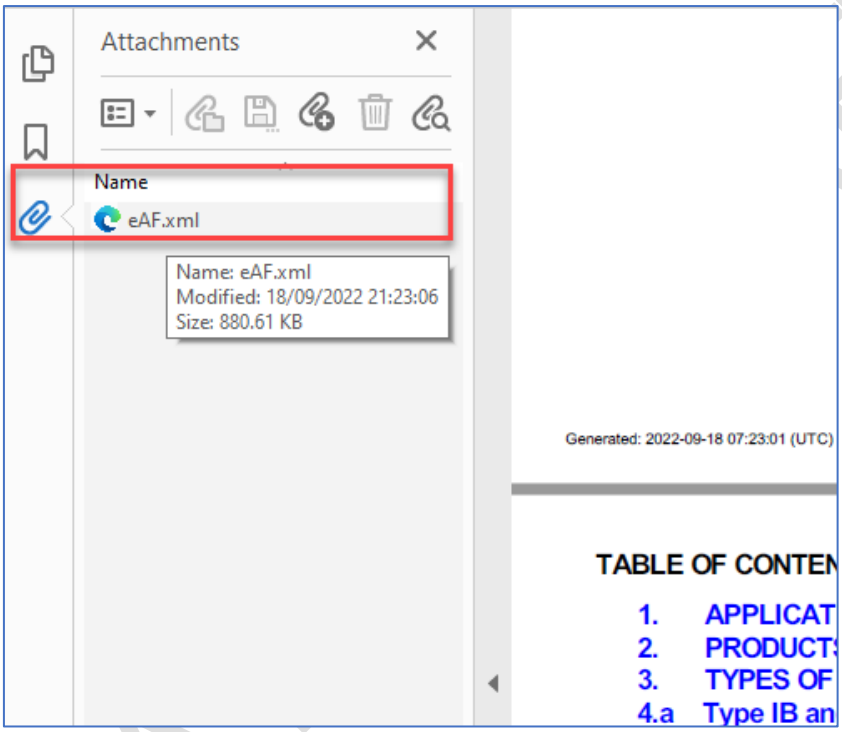


Figure 97 - FHIR xml

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 98 - XML file - Document Tree

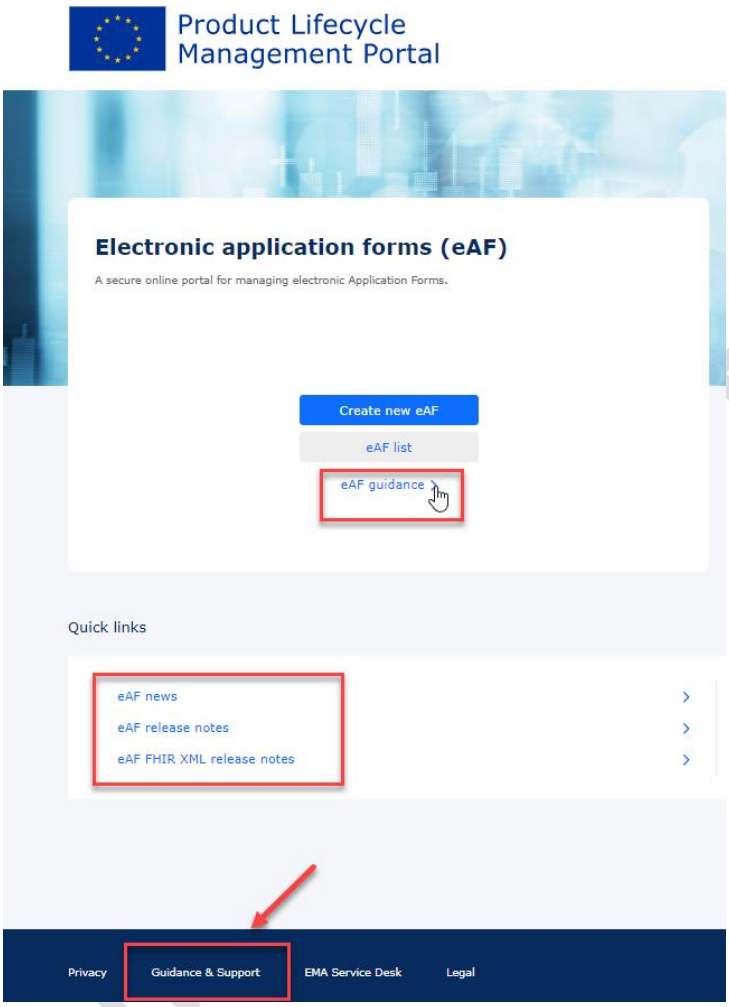
3.2. *PDF Requirements*

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.



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.

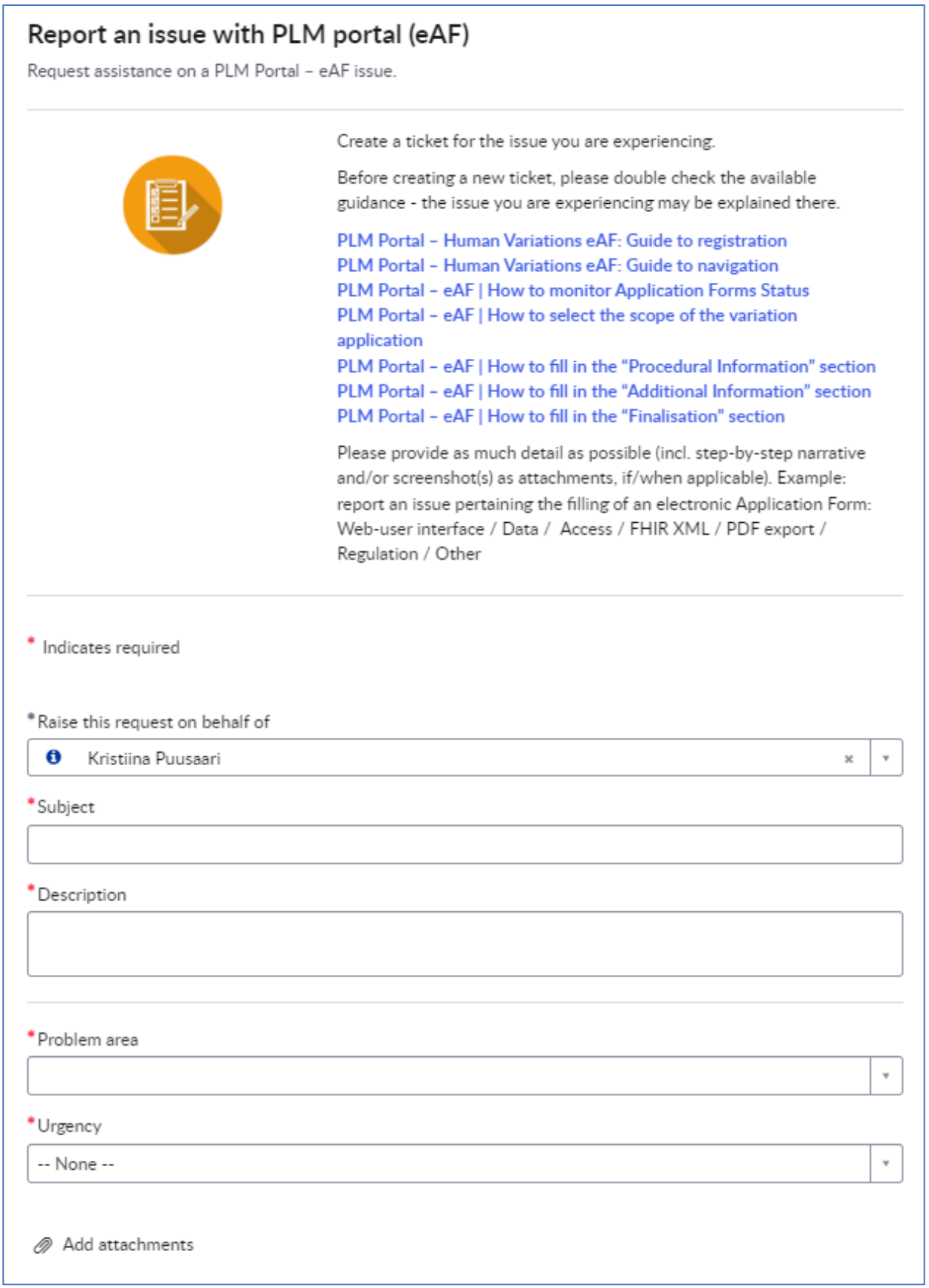


Figure 99 - Report an Issue with PLM Portal (eAF) Form

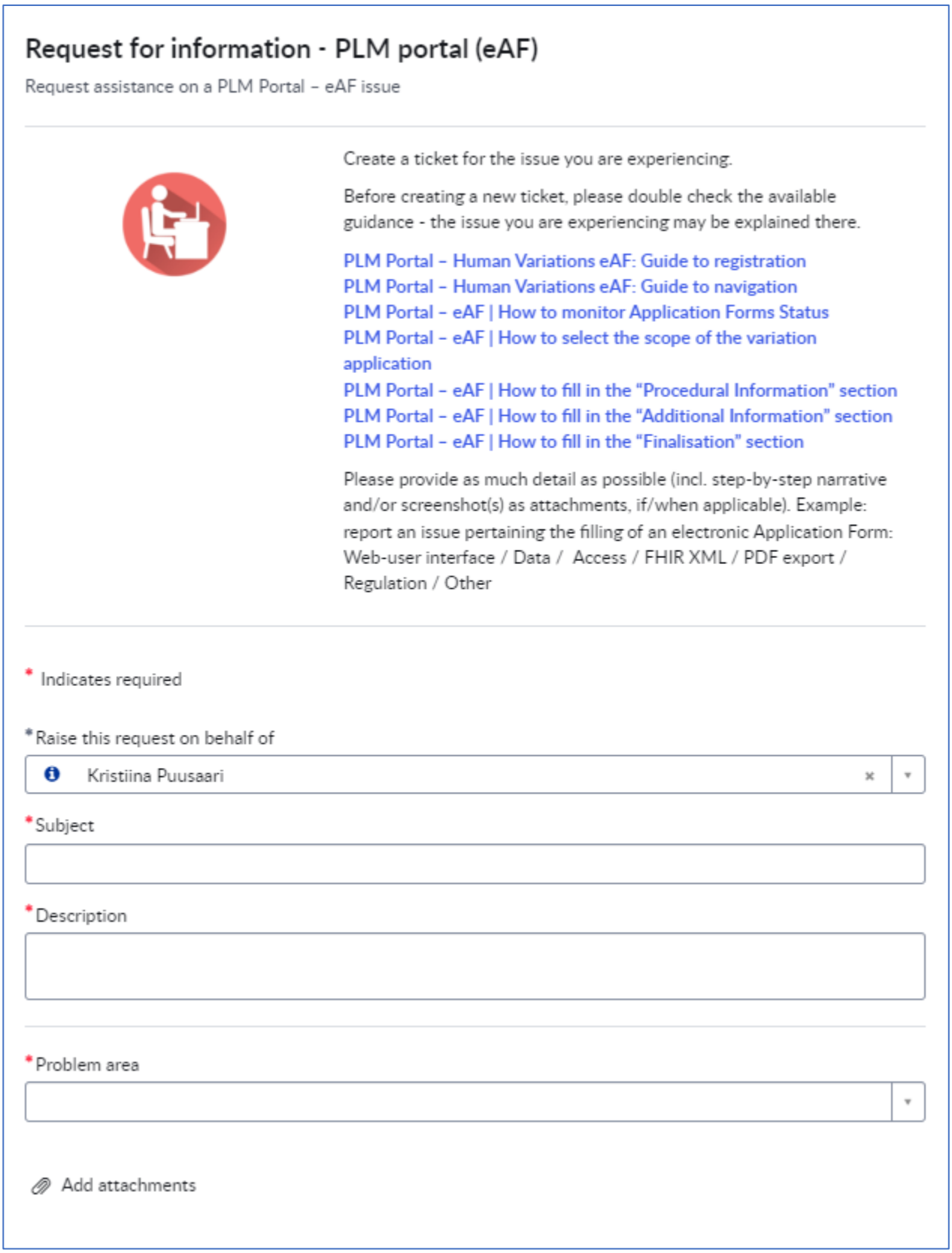


Figure 100 - Request for Information - PLM Portal (eAF) Form

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.

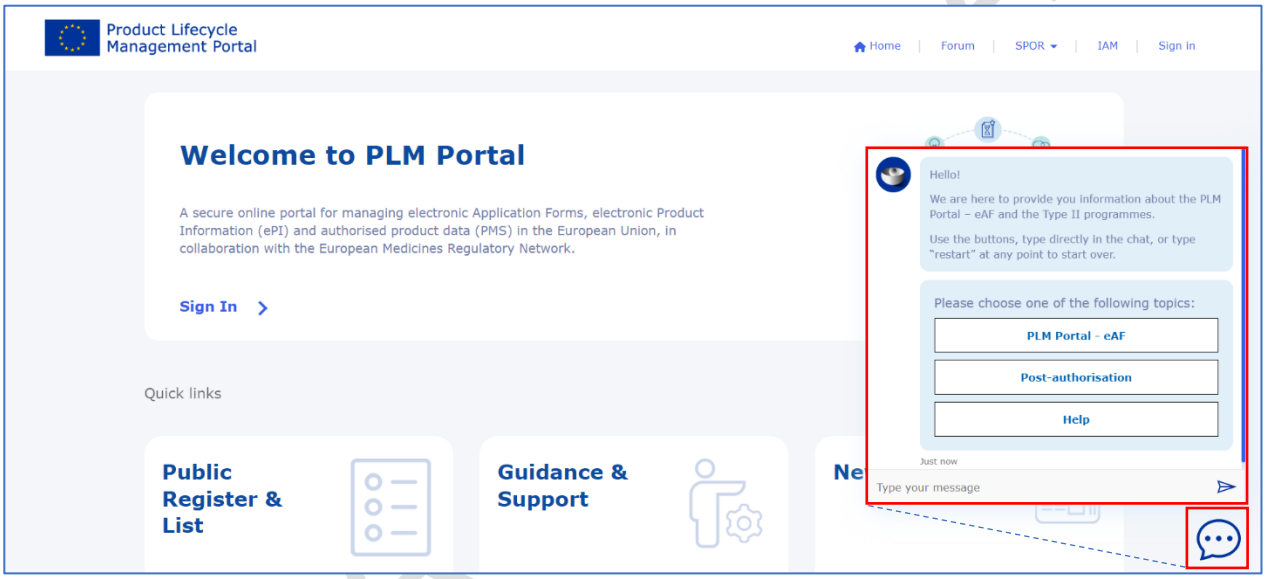


Figure 101 - PLM Chatbot