



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Product Lifecycle Management Portal – Human Variations eAF Guide to navigation

Version 1.0

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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
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 this is 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: <link>.

- In UAT environment, the PLM Portal - eAF can be accessed via the following link:
<https://euema-prs-uat.powerappsportals.com/>.

You must click on the **Sign In** button, which is available at the centre-left or at the top right corner of the PLM Portal - eAF home page.

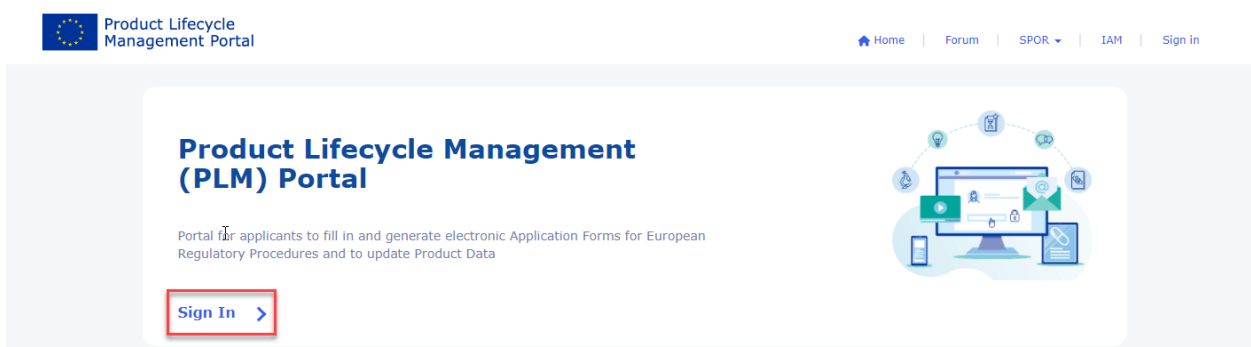


Figure 1 - Sign-in

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 in to the PLM Portal – eAF
2. On the home page, top navigation bar, click on "Application Forms"

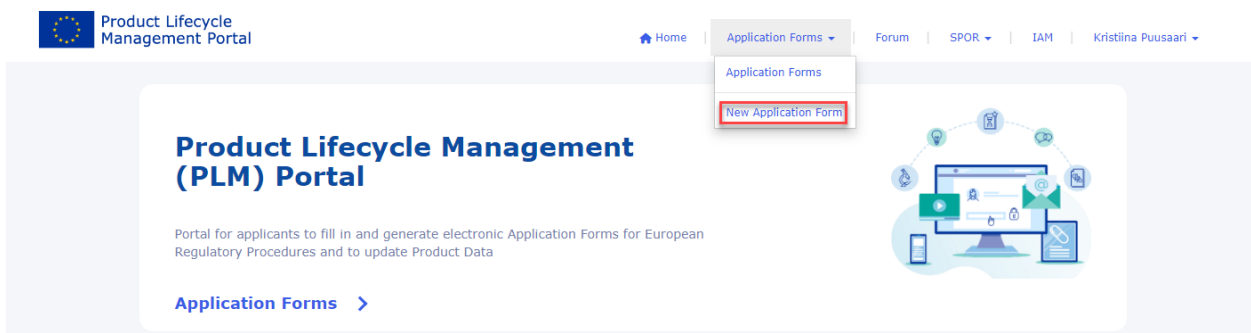



Figure 2 - New Application Form

3. Click on [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:

4. Add an **Application Form Type**, by using the  icon (currently only possible to select the *Variation Form Human*)

Select Application Form Type ×

Search 

Choose one record and click Select to continue


✓ Name ↑	Description	Domain
<input checked="" type="checkbox"/> Variation Form Human	Application for variation to a marketing authorisation	Human use

Select **Cancel** **Remove value**


5. 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. Please note that for now, the Friendly name **cannot** be updated or changed. Try and make it meaningful so that you can find your variation form again if needed.

[Home](#) > [Application Forms](#) > [Draft Application Form](#)


1 Select Application Details **2 Add Co-Author**

Application Form Type * × 

Friendly Name *

Reference MAH ⓘ 

Create & Next **Cancel**

6. 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.

Select Reference MAH

Q

Choose one record and click Select to continue

✓ Organisation Name ↑	Full address	Organisation Id	Organisation Location
<input checked="" type="checkbox"/> European Medicines Agency	P. O. Box 71010 1008 BA Amsterdam Netherlands	ORG-100013412	LOC-100020260

Select
Cancel
Remove value

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.

[Home](#) > [Application Forms](#) > [Draft Application Form](#)

1 Select Application Details
2 Add Co-Author

Application Form Type *

Friendly Name *

Reference MAH ⓘ *

Q

Org ID

ORG-100013412

Address

P. O. Box 71010
Amsterdam 1008 BA
Netherlands

LOC ID

LOC-100020260

Customer Account Number

—

Modified On

13/09/2022 07:09

Create & Next
Cancel

7. Click on the Create & Next button

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:

8. 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)

You can also see a very important note related to Commercially Confidential Data (CCI) on this screen.

Home > Application Forms > Draft Application Form

1 Select Application Details ✓ 2 Add Co-Author

Info

Adding an applicant Manager will share all products contained within this application including commercially confidential information and product data from SPOR Product Management System (PMS).
Adding an applicant contributor will share all products contained within all applications of this organisation including commercially confidential information and product data from SPOR Product Management System (PMS).

Full Name	Contact Email	Role ↑	Role Status ⓘ
Kristiina Puusaari	Kristiina.Puusaari@ema.europa.eu	EMA Admin Assistant	Affiliated

Add Co-author

Previous **Next** **Close**

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.

From My Organisation Affiliate(s) From Other Organisation(s)

Column visibility Search Co-authors

	Full Name	Role	Email
<input type="checkbox"/>	[Redacted]	Applicant Manager	[Redacted]
<input checked="" type="checkbox"/>	[Redacted]	Applicant Manager	[Redacted]
<input type="checkbox"/>	[Redacted]	Applicant Manager	[Redacted]
<input type="checkbox"/>	[Redacted]	Applicant Manager	[Redacted]
<input type="checkbox"/>	[Redacted]	Applicant Contributor	[Redacted]
<input checked="" type="checkbox"/>	[Redacted]	Applicant Manager	[Redacted]
<input type="checkbox"/>	[Redacted]	Applicant Manager	[Redacted]

Showing 1 to 7 of 7 entries 0 items selected

Save **Cancel**

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.

9. 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.

Automated notifications are **not sent** when co-authors are added.

You can send an email notification directly from the system to co-Author(s) from other organisations whose role status is set to 'pending'. This will alert the added co-author that they have been added to the application form.

Home > Application Forms > Draft Application Form > Add Co-author

i **Info**
Adding an applicant Manager will share all products contained within this application including commercially confidential information and product data from SPOR Product Management System (PMS).
 Adding an applicant contributor will share all products contained within all applications of this organisation including commercially confidential information and product data from SPOR Product Management System (PMS).

From My Organisation Affiliate(s)

From Other Organisation(s)

Search User by E-Mail

ema.eu

Q

i

Full Name

Contact E-Mail

a.europa.eu

Save

Cancel

View/Manage Co-Author

Those added co-authors from other organisations who have role Status '**Pending**' should receive a notification e-mail asking for the submission of 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.

Home > Application Forms

Draft Deactivated Completed All Column visibility Refresh Download

puu + Create New Application Form

Application Form Id	Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	Modified On (Access Date)	Status
	KP 02/11/22 TestPill Type IA	Variation Form Human	European Medicines Agency	Kristiina Puusaari	02/11/2022 10:59	Kristiina Puusaari	02/11/2022 11:01	Draft
	KP 02/11/22 grouping	Variation Form Human		Kristiina Puusaari	02/11/2022 08:14	Kristiina Puusaari	02/11/2022 10:33	
	KP 02/11/22 retest co-author	Variation Form Human	European Medicines Agency	Kristiina Puusaari	02/11/2022 10:18	Kristiina Puusaari	02/11/2022 10:28	
	KP 02/11/22	Variation Form Human	European Medicines Agency	Kristiina Puusaari	02/11/2022 08:20	Kristiina Puusaari	02/11/2022 08:26	Draft

Home > Application Forms > View/Manage Co-Author

Info
Adding an applicant Manager will share all products contained within this application including commercially confidential information and product data from SPOR Product Management System (PMS). Adding an applicant contributor will share all products contained within all applications of this organisation including commercially confidential information and product data from SPOR Product Management System (PMS).

Add Co-author

Full Name	Contact Email	Role	Role Status
Kristiina Puusaari	Kristiina.Puusaari@ema.europa.eu	EMA Admin Assistant	Affiliated

Close

View/Manage Co-authors

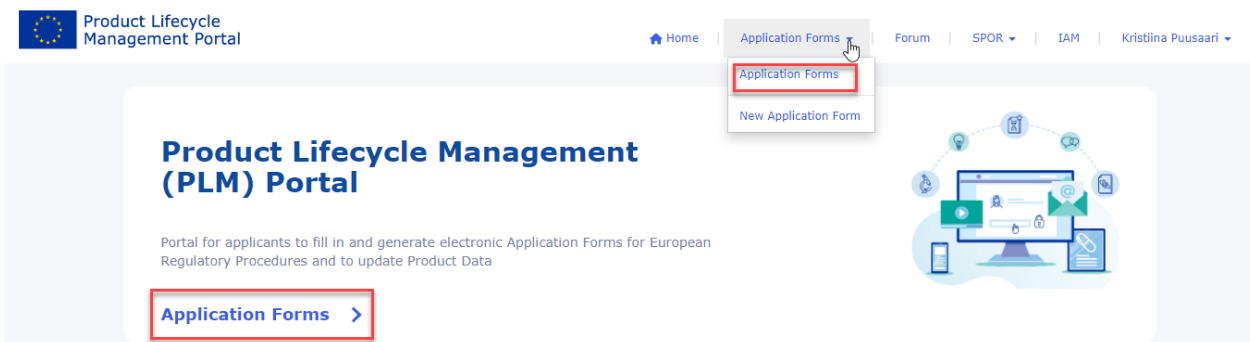
2.1.3. How to access previous created/edited electronic Application Form(s)

Industry users with an active EMA account and with the eAF **Applicant Manager** role can edit an existing Application Form which has been created by themselves;

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

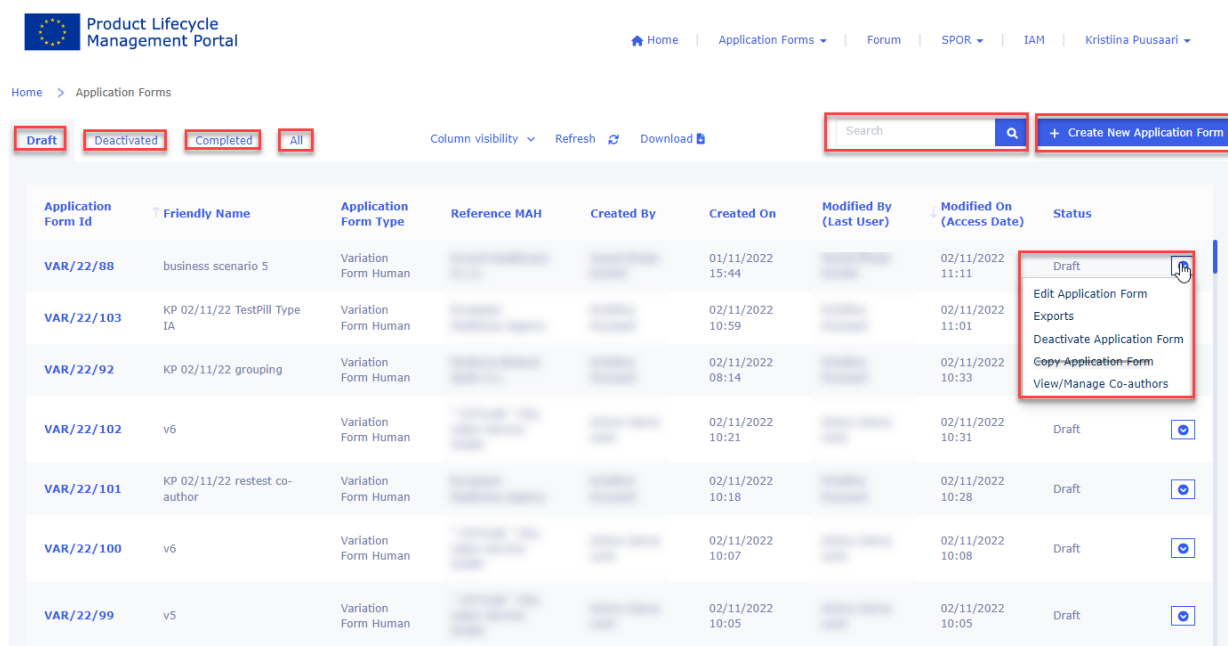
NCA users with an active EMA account and with the eAF Competent Authority User role can edit any existing Application Form from their Member State.

1. Sign into the PLM Portal - eAF
2. On the home page, top navigation bar, click on Application Forms or navigate directly from the 'Application forms' link in the middle of the screen
3. Click on Application Forms
4. Explain super clearly how to reopen for editing after the form has been finalised




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

- 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.




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.

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	Industry user(s)			NCA user(s)
	(UAT) eAF Applicant Contributor	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	(UAT) eAF Competent Authority User
Application Form Status/tab				
Draft	<ul style="list-style-type: none"> - Edit Application Form - Exports - View/Manage Co-authors 	<ul style="list-style-type: none"> - Edit Application Form - Exports - Deactivate Application Form - Copy Application Form* - View/Manage Co-authors 		
Deactivated	<ul style="list-style-type: none"> - View Application Form - View Co-authors - Exports 	<ul style="list-style-type: none"> - View Application Form - View Co-authors - Exports - Copy Application Form* - Reopen Application Form - Delete Application Form* 		
Completed	<ul style="list-style-type: none"> - View Application Form - View Co-authors - Exports 	<ul style="list-style-type: none"> - View Application Form - View Co-authors - Exports - Reopen Application Form - Copy Application Form* - Deactivate Application Form 		

User	Industry user(s)	NCA user(s)
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* – it generates a [FHIR PDF](#) file, FHIR standards complaint, and a [Validation XML](#) file, containing encountered errors in the selected Application Form as it has been filled in,
- *View Co-authors* – it provides a (read-only) list of all previously added co-authors onto a given Application Form;
- *View/Manage Co-authors* – it provides a list of all previously added co-authors onto a given Application Form, allowing to manage that list (delete 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* – it provides a (read-only) view of that Application Form in terms of Product Selection, Type(s) of change(s), Procedural Information, Proposed Changes and Finalisation;
- *Edit Application Form* – to enter into that Application Form and insert/update its details;
- *Copy Application Form* – it creates a separate copy of that Application Form (please note that this feature is currently **not available**);
- *Deactivate Application Form* – it 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 be completely deleted (the delete function is not currently available). 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* – it updates the Application Form status to Draft, allowing editing on 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** – when 'delete application form' is clicked, the form moves back under the 'Draft' tab.

Note: At the time of go-live it is not yet possible to 'clone' or copy an application form. This feature has been requested by multiple testers and once the requirements are clarified this feature could be added in future.

While the Copy Application Form feature is not yet available, it may be tempting to edit previously created application form (that has been already submitted for a different procedure), especially if the form contains the same products and similar scopes, for a purpose of using this form for another

procedure. Please note that if you make changes to a form that has been previously submitted for another procedure and are subsequently asked by the EMA to update the form during business validation/during the ongoing procedure for the originally submitted variation, you will need to make further edits to ensure that the originally provided information hasn't changed and only the requested changes have been made.

Draft and completed forms have retention period of 104 wks (2years).

2.1.4. Copy form function

The copy form function is currently not available

2.1.5. Delete form function

The delete form function is currently not 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 or (ii) at any other point in time, after having created the Application Form.

- For (i), please follow the instructions on section 2.1.2 How to create a new electronic Application Form;

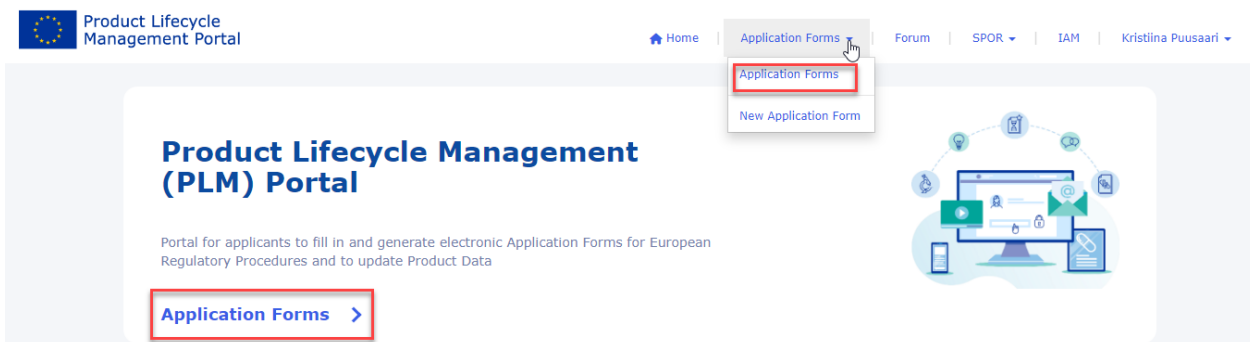
2.1.7. For (ii), please follow the instructions on section 2.1.3 How to access previous created/edited electronic Application Form(s)

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

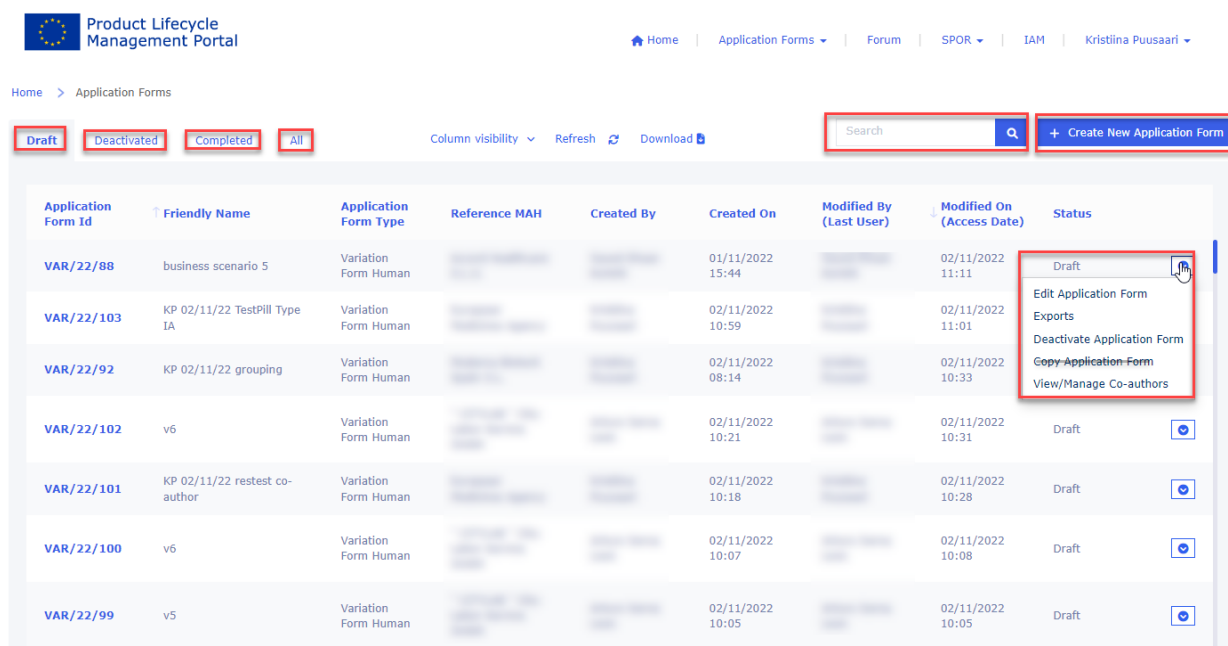
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Depending on your access role(s)/permissions, you will see a given list of Application Forms:

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- eAF Applicant Manager role - Application Form(s) created by you or in which you were added as co-author;
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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.

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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:

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User Role name	Industry user(s)			NCA user(s)
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User	Industry user(s)	NCA user(s)
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* – it generates a [FHIR PDF](#) file, FHIR standards complaint, and a [Validation XML](#) file, containing encountered errors in the selected Application Form as it has been filled in,
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- *Reopen Application Form* – it updates the Application Form status to Draft, allowing editing on that same Application Form;
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Draft and completed forms have retention period of 104 wks (2years).

2.1.8. Copy form function

The copy form function is currently not available

2.1.9. Delete form function

The delete form function is currently not available

2.2. Product Selection


2.2.1. How to add a product in an Application Form

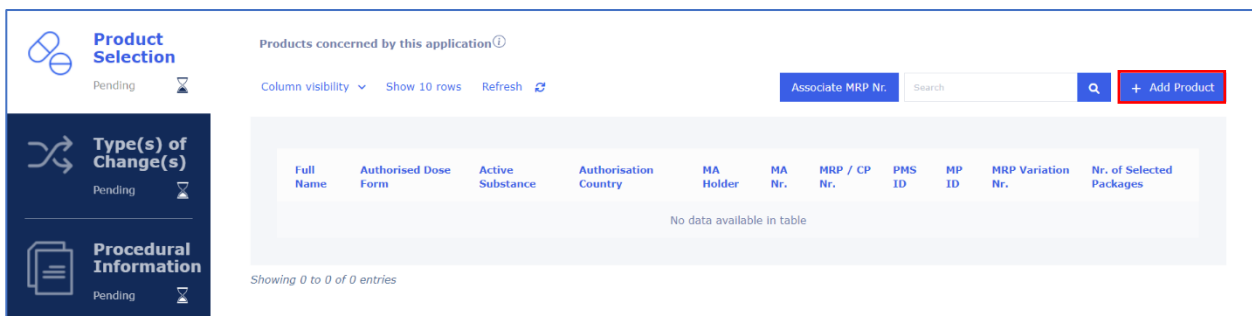
Industry users with the eAF Applicant Manager role or the eAF Applicant Coordinator role and NCA users with the eAF Competent Authority User role may add/delete products from an Application Form.

The insertion 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 2.1.1, 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.

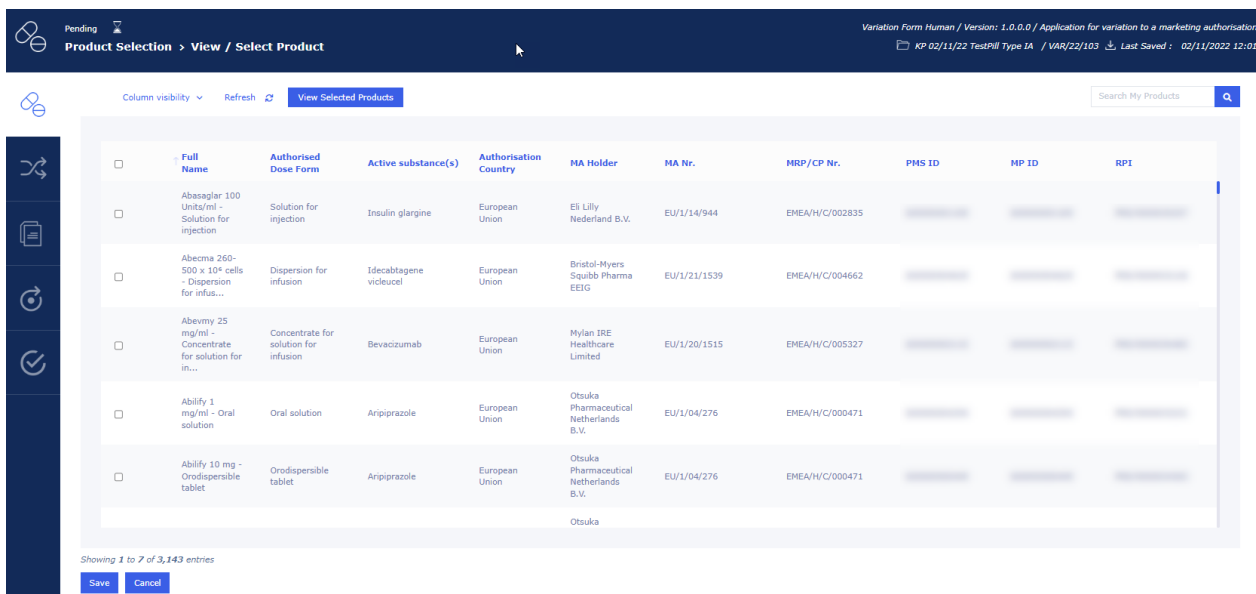
Please note that the 'search' field with the magnifying glass  is not a search field but find products, but to 'filter' a list of already selected products (this can be only used when editing a form that already has some products selected). Products cannot be searched/added using this field.



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.



Product Selection > View / Select Product

Column visibility ▾ Refresh ↻ View Selected Products

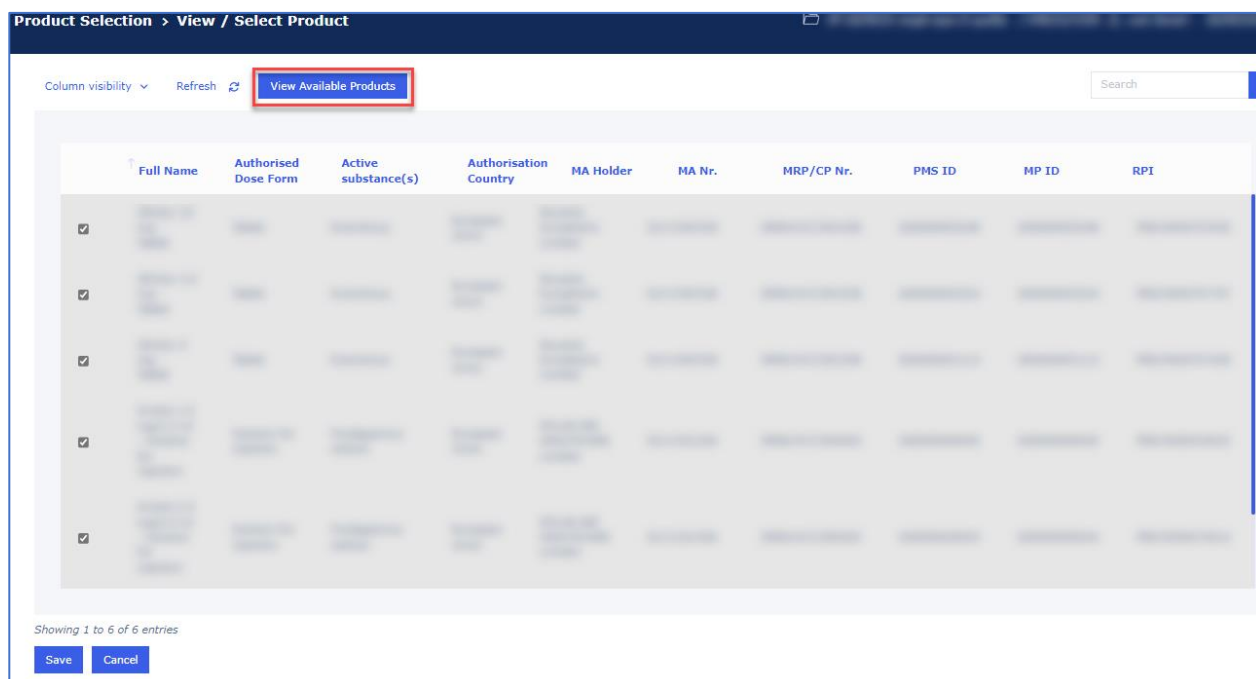
Search My Products 🔍

	Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
<input type="checkbox"/>	Abasaglar 100 Units/ml - Solution for injection	Solution for injection	Insulin glargine	European Union	Eli Lilly Nederland B.V.	EU/1/14/944	EMEA/H/C/002835			
<input type="checkbox"/>	Abeema 260-500 x 10 ⁶ cells - Dispersion for infus...	Dispersion for infusion	Idecabtagene vicleucel	European Union	Bristol-Myers Squibb Pharma EEIG	EU/1/21/1539	EMEA/H/C/004662			
<input type="checkbox"/>	Abevmy 25 mg/ml - Concentrate for solution for infusion	Concentrate for solution for infusion	Bevacizumab	European Union	Mylan IRE Healthcare Limited	EU/1/20/1515	EMEA/H/C/005327			
<input type="checkbox"/>	Abilify 1 mg/ml - Oral solution	Oral solution	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471			
<input type="checkbox"/>	Abilify 10 mg - Orodispersible tablet	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471			

Showing 1 to 7 of 3,143 entries

Save Cancel

- 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.



Product Selection > View / Select Product

Column visibility ▾ Refresh ↻ View Available Products

Search 🔍

	Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
<input checked="" type="checkbox"/>										
<input checked="" type="checkbox"/>										
<input checked="" type="checkbox"/>										
<input checked="" type="checkbox"/>										
<input checked="" type="checkbox"/>										

Showing 1 to 6 of 6 entries

Save Cancel

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.

4. Click on the [Save](#) button

5. 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.

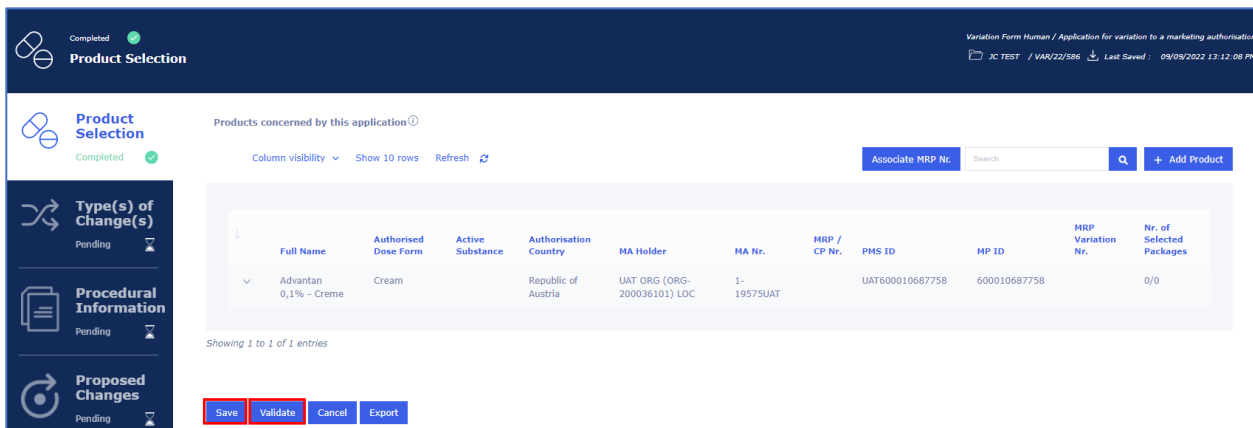
Please note that you **cannot** select the presentations in this view, you can simply view them. The linking of the packaged medicinal product and the scope is done in the Proposed Changes section (Present and Proposed).


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

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr. ①	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
 Arixtra 1.5 mg/0.3 ml - Solution for injection	Solution for injection	Fondaparinux sodium	European Union	Mylan IRE Healthcare Limited	EU/1/02/206	EMEA/H/C/000403	6000000000045	6000000000045		0/7
Selected Packaged Medicinal Product(s) <input type="text" value="Search"/>										
Full Name	Pack Size	MA Number	MRP / CP Number	PMS ID	Authorisation Status					
<input type="checkbox"/> Arixtra 1.5 mg/0.3 ml - Solution for injection	10 pre-filled syringes	EU/1/02/206/025			Valid					
<input type="checkbox"/> Arixtra 1.5 mg/0.3 ml - Solution for injection	10 pre-filled syringes	EU/1/02/206/007			Valid					
<input type="checkbox"/> Arixtra 1.5 mg/0.3 ml - Solution for injection	2 pre-filled syringes	EU/1/02/206/024			Valid					
<input type="checkbox"/> Arixtra 1.5 mg/0.3 ml - Solution for injection	20 pre-filled syringes	EU/1/02/206/026			Valid					
<input type="checkbox"/> Arixtra 1.5 mg/0.3 ml - Solution for injection	7 pre-filled syringes	EU/1/02/206/006			Valid					
<input type="checkbox"/> Arixtra 1.5 mg/0.3 ml - Solution for injection	2 pre-filled syringes	EU/1/02/206/005			Valid					
<input type="checkbox"/> Arixtra 1.5 mg/0.3 ml - Solution for injection	20 pre-filled syringes	EU/1/02/206/008			Valid					


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 the selected products not needed in this application. 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.





Completed  **Product Selection**

Variation Form Human / Application for variation to a marketing authorisation
JC TEST / VAN/22/586 Last Saved : 09/09/2022 13:12:08 PM

Product Selection
Completed 

Products concerned by this application ⓘ


Column visibility Show 10 rows Refresh 


Associate MRP Nr. Search  + Add Product


Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP / CP Nr.	PHS ID	MP ID	HRP Variation Nr.	Nr. of Selected Packages
Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG-200036101) LOC	1-1957SUAT		UAT600010687758	600010687758		0/0

Showing 1 to 1 of 1 entries

Save **Validate** **Cancel** **Export**

Type(s) of Change(s)
Pending 

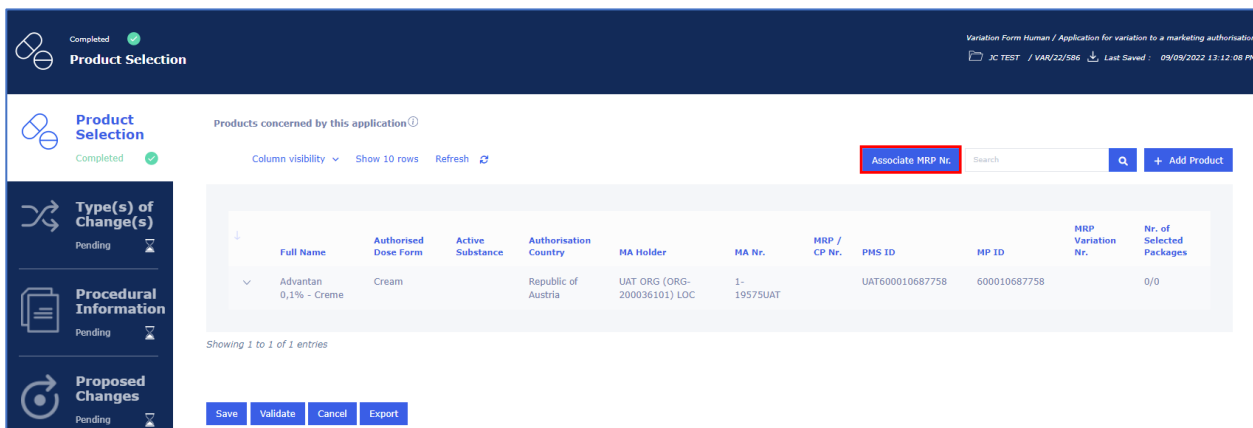
Procedural Information
Pending 


Proposed Changes
Pending 

2.2.2. 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.

- Access an existing or create a new Application Form. See sections 2.1.1, 2.1.2 and 2.1.3 for further details
- In the Product Selection page, click on the **Associate MRP Nr.** button





Completed  **Product Selection**

Variation Form Human / Application for variation to a marketing authorisation
JC TEST / VAN/22/586 Last Saved : 09/09/2022 13:12:08 PM

Product Selection
Completed 

Products concerned by this application ⓘ


Column visibility Show 10 rows Refresh 


Associate MRP Nr. Search  + Add Product


Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP / CP Nr.	PHS ID	MP ID	HRP Variation Nr.	Nr. of Selected Packages
Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG-200036101) LOC	1-1957SUAT		UAT600010687758	600010687758		0/0

Showing 1 to 1 of 1 entries

Save **Validate** **Cancel** **Export**

Type(s) of Change(s)
Pending 

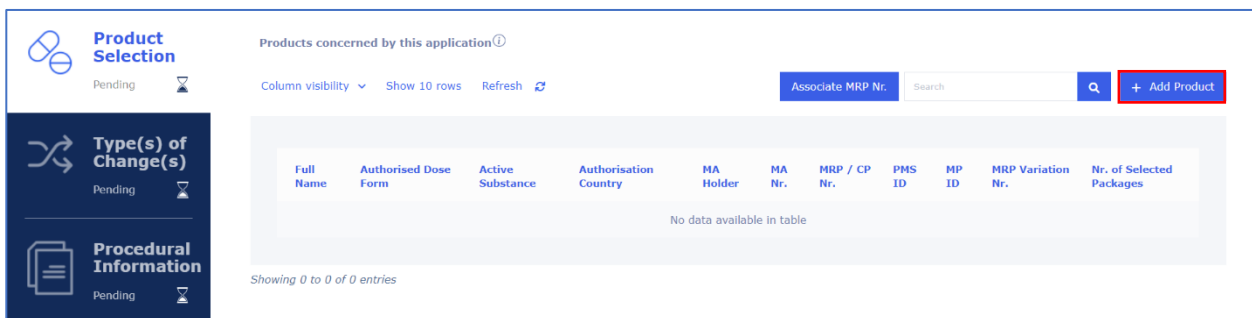
Procedural Information
Pending 

Proposed Changes
Pending 

2.2.3. 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.

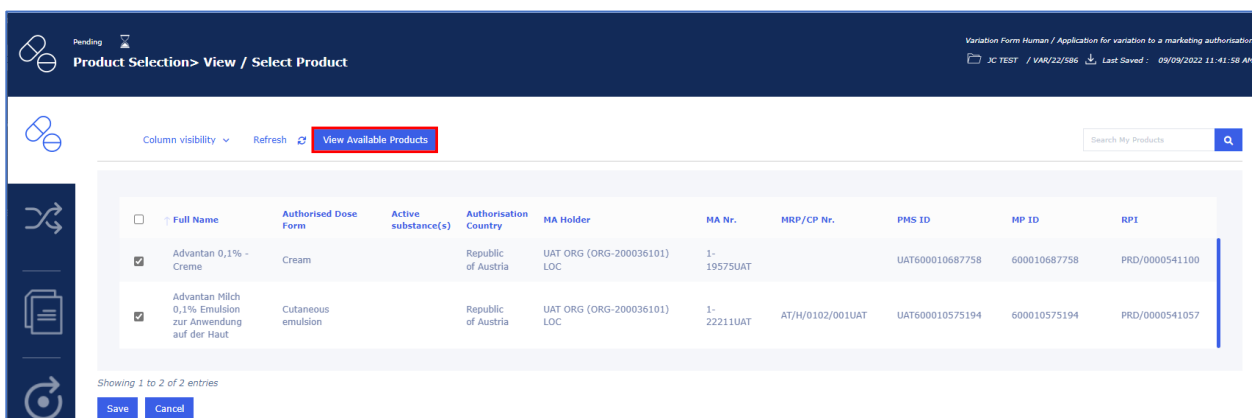
- Access an existing or create a new Application Form. See sections 2.1.1, 2.1.2 and 2.1.3 for further details
- In the Product Selection page, click on **+ Add Product**



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.



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)

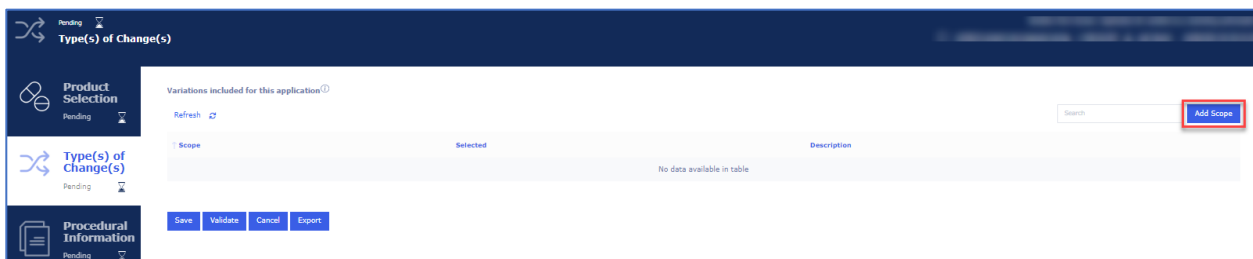
2.3.1. How to add a variation scope in an Application


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.

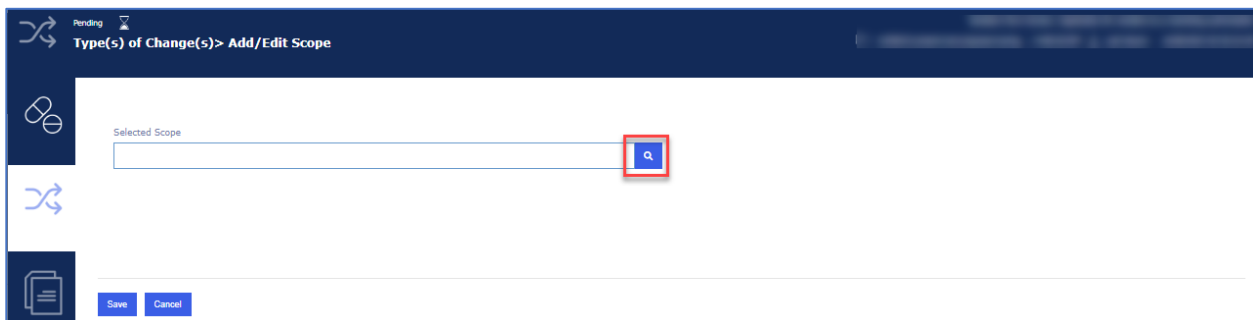
The insertion of scopes is logically the next step when filling in the web form. The selection of the scopes in the web form is comparable to filling in the first part of section 3 of the interactive pdf variation eAF.

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 2.1.1, 2.1.2 and 2.1.3 for further details
2. In the Type(s) of Change(s) page, click on **Add Scope**

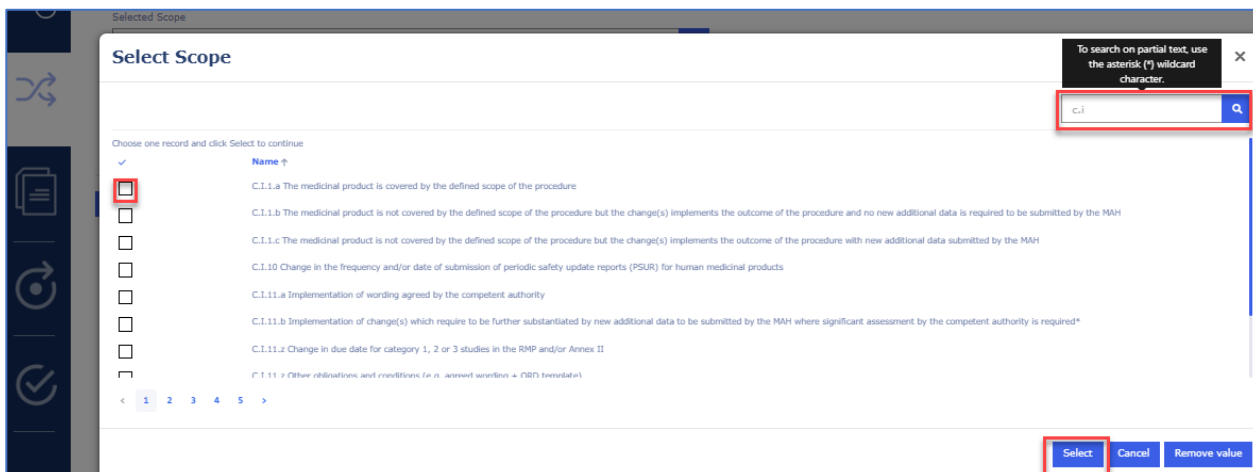


3. In the Add/Edit Scope subpage, launch the search for scope selection by clicking on the magnifying glass . The scopes cannot be searched in Add/Edit scope subpage. Clicking the magnifying glass will open the 'Select scope window where you can select the scope by filtering the list.



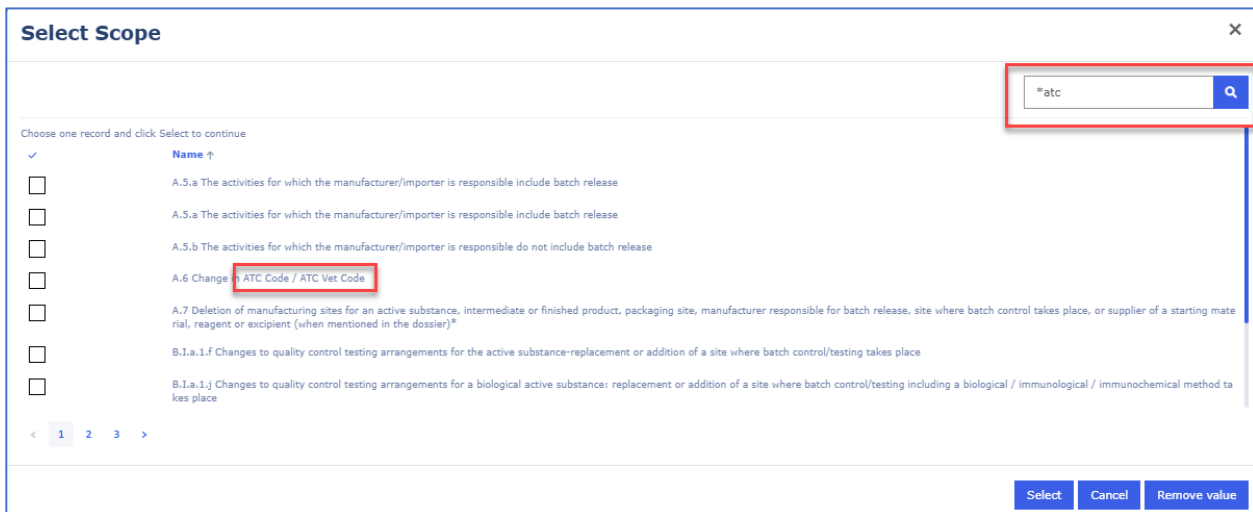
4. In the 'Select Scope' window you will be presented a list of scopes with multiple pages to navigate to. The **easiest and quickest** way to select the scope is by **typing** the scope in the search field. The more you type, the further the list will be filtered making it easier to select the correct scope (the list is not autofiltered, 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 look using the 'text' part of the scope, please note that you need to add an asterisk (*) 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.



The screenshot shows the 'Select Scope' window. At the top right, a tooltip says 'To search on partial text, use the asterisk (*) wildcard character.' The search bar contains 'C.I'. Below the search bar, a list of scopes is displayed. The first item, 'C.I.1.a The medicinal product is covered by the defined scope of the procedure', has its checkbox selected. At the bottom right, there are three buttons: 'Select', 'Cancel', and 'Remove value'.

Example of search using classification code




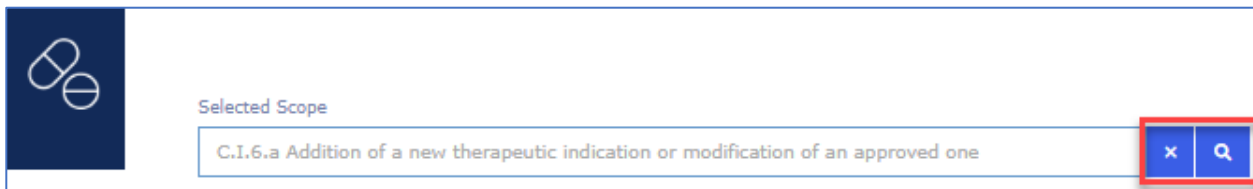
The screenshot shows the 'Select Scope' window. The search bar contains '*atc'. The search results list various scope categories. The item 'A.6 Change' has its checkbox selected. A red box highlights the search bar and the 'Select' button. The 'ATC Code / ATC Vet Code' column is visible for the selected item.

Example of search using wild card and text

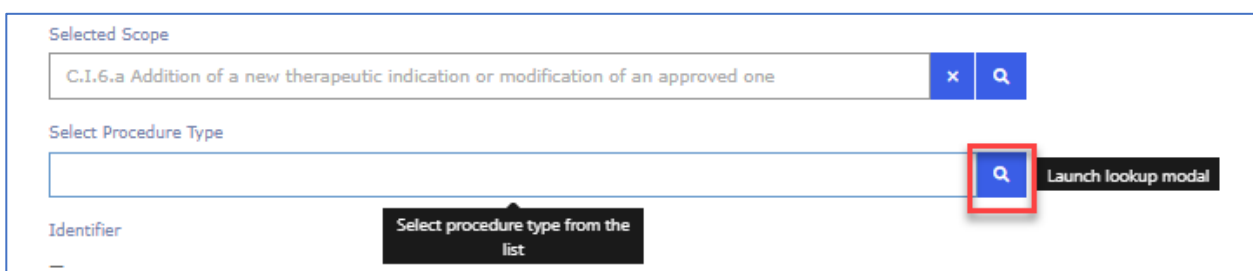
5. Select the needed classification code (scope), this is easily done by simply clicking anywhere in the row, it is **not** necessary to use the tick box, this will be ticked when you click anywhere on the row. Please note that you can only select **one scope at the time**. Currently it is **not possible to clone/copy** the selected scopes, however, a change request has been raised to be able to easily add/clone the same scopes multiple times.

- 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 screen

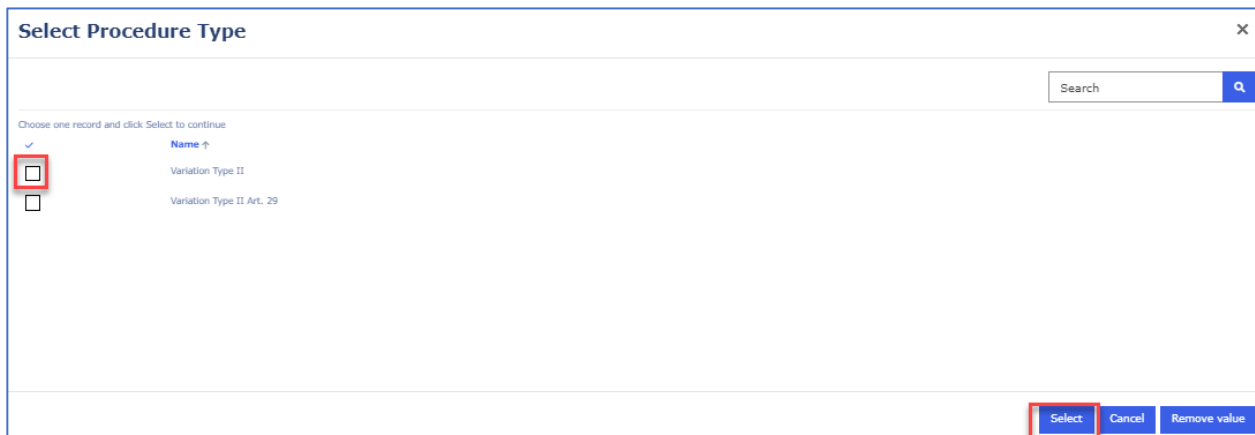


- Click on the magnifying glass  to 'Select Procedure Type'

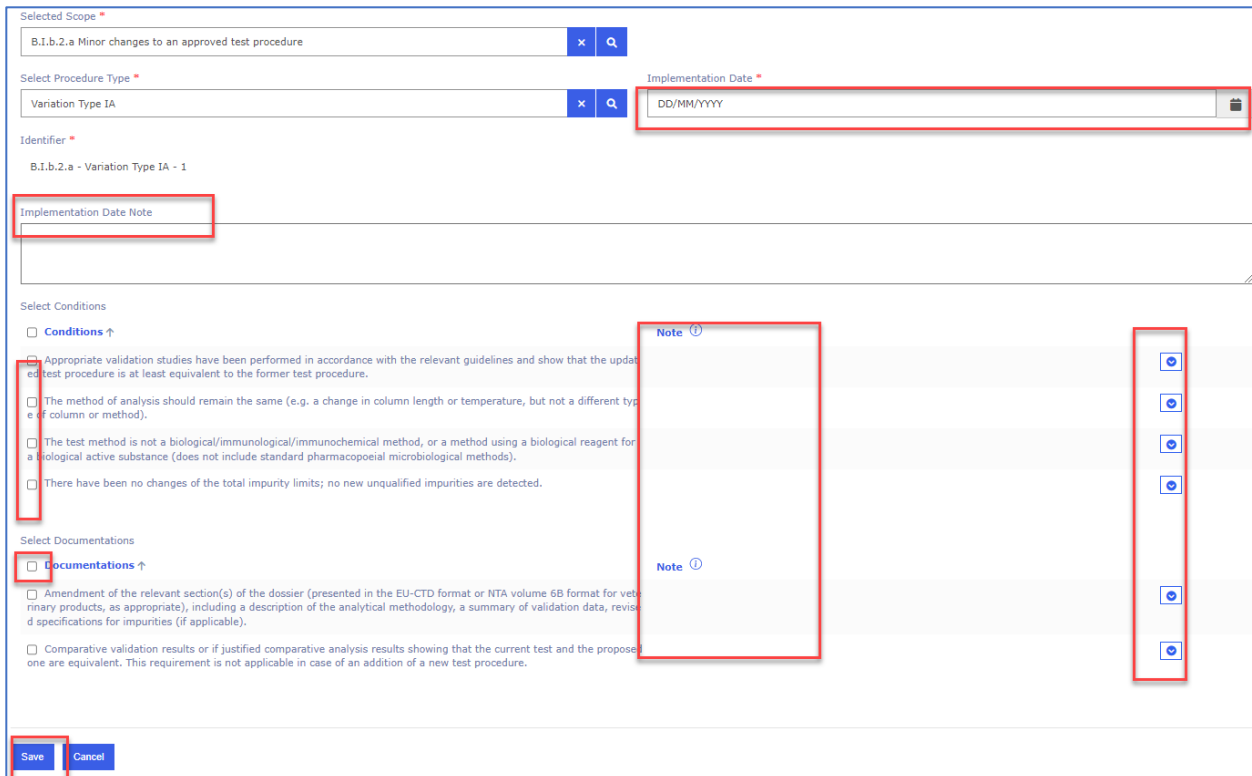


A list of available Procedure Types will be displayed. You can only select one procedure type from the list. The list can be filtered using the search bar on the top right-hand corner.

- 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 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



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



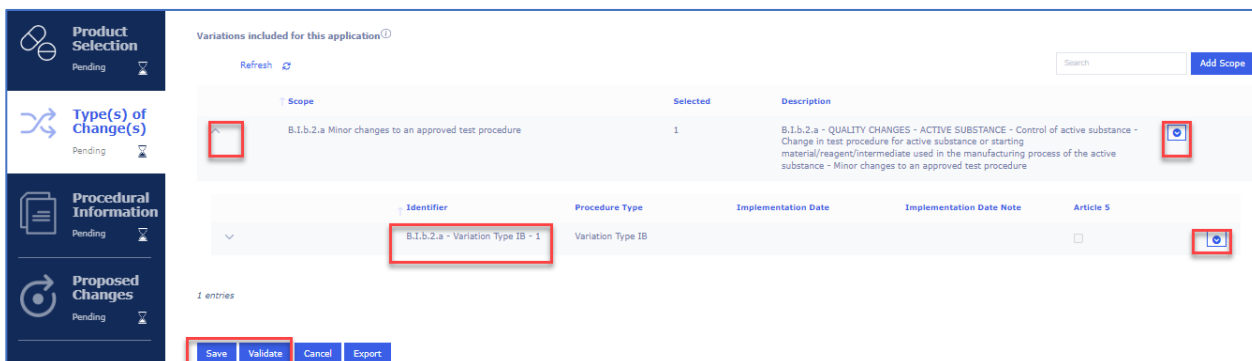
For Type IA/Type IA_{IN} you need to add an Implementation date (either by selecting it from a calendar or by providing the date in format DD/MM/YYYY e.g.: 31/12/2022). Alternatively, or in addition, you can also provide an Implementation Date Note (free text field). For Type IA/Type IA_{IN} it is mandatory 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 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.

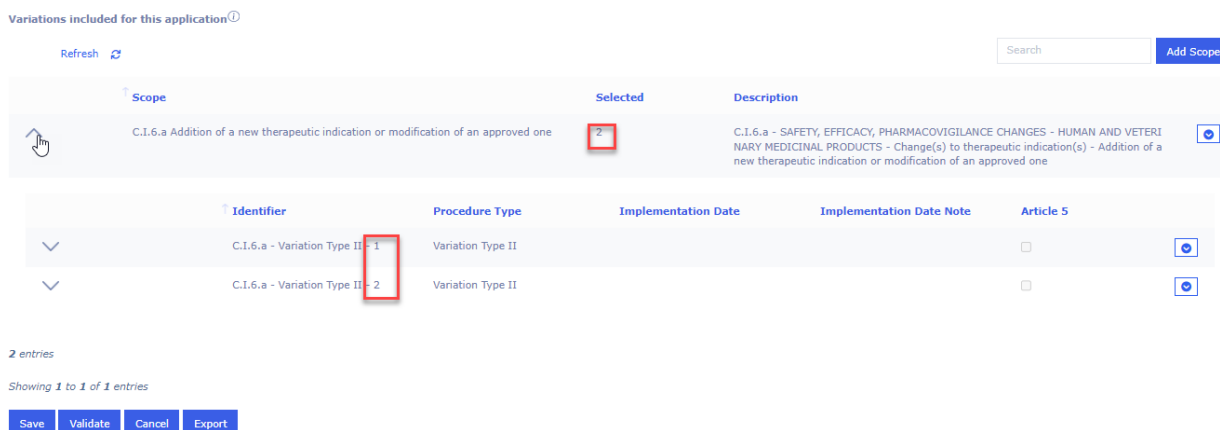
- Click the **Save** button to save your selection. If you do not wish to save your selection, you can press the **Cancel** button.

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



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. Repeat the step by clicking 'Add scope' button. You can do this as many times as needed. Please note that it is **not possible to copy/clone scope/procedure type combinations** in this version of the form.
12. Please note that if the same scope is added multiple times, 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.

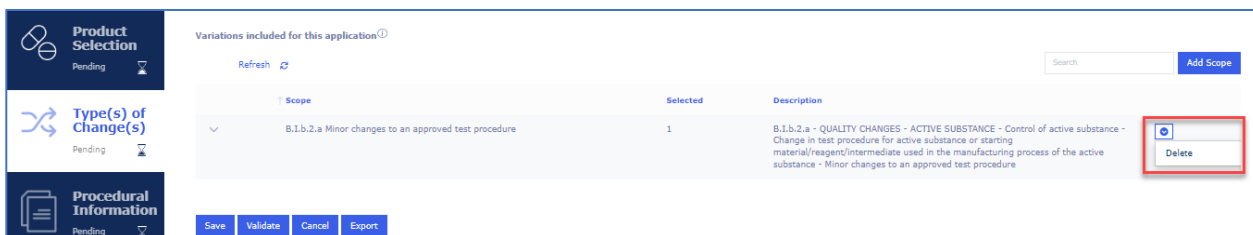


13. Click on the **Save** button to ensure that you save the changes you made i.e. to save the selected scope(s). You may want to click on the **Validate** button to change the status of this section to **Completed**.

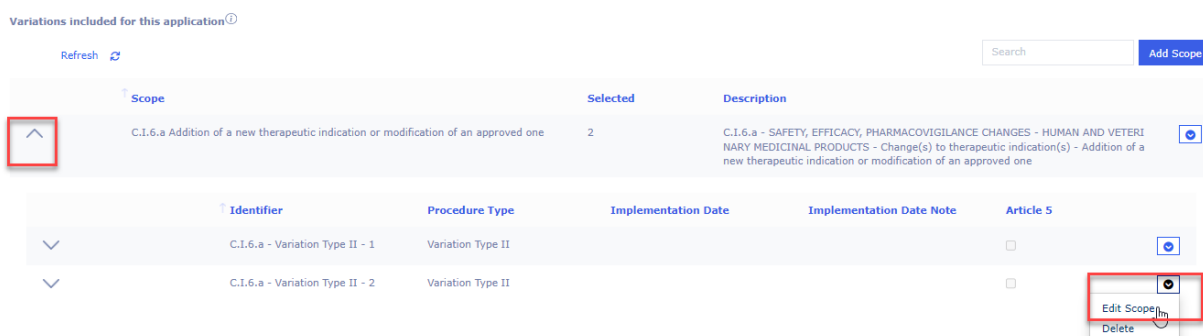
2.3.2. How to delete a scope in an application

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

1. Access an existing or create a new Application Form. See sections 2.1.1, 2.1.2 and 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'.

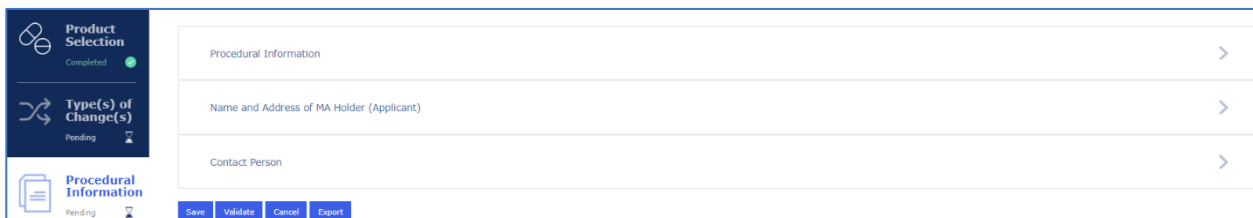


If you only wish to change the procedure type, for example from Type IA to Type IB, please expand the selection using the down arrow and click to 'Edit/view' scope.



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).

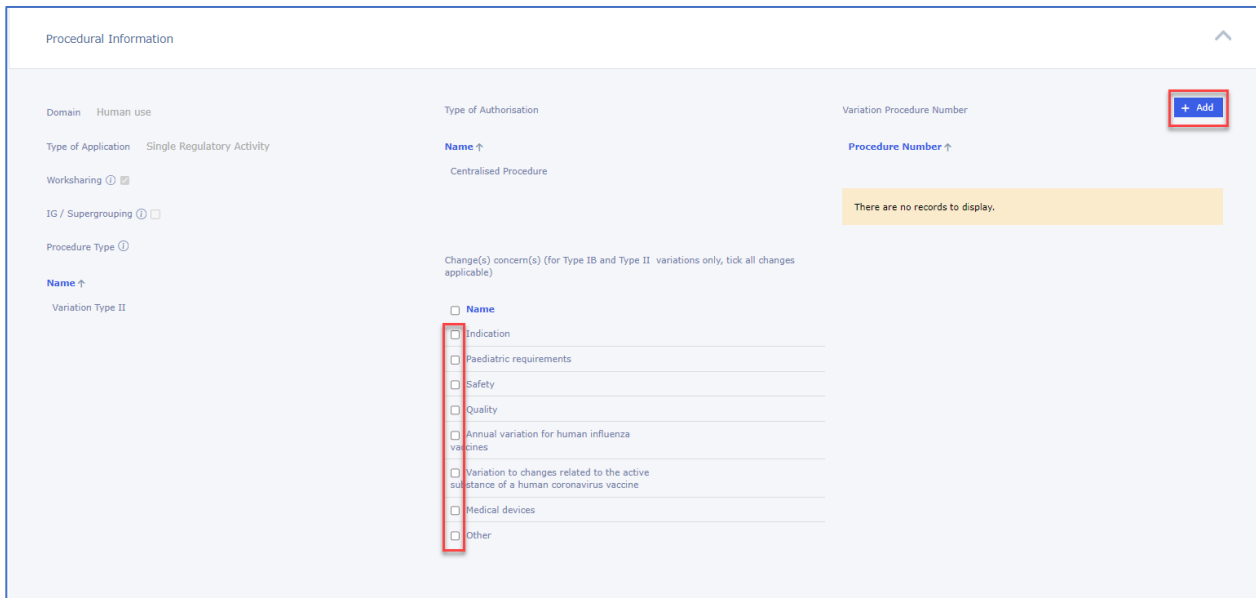


2.4.1. Procedural Information

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.



- Domain: This is always 'Human Use' as the variation form only contains human medicinal products.

NOTE: The current version of the form (November 4th release) has a technical limitation which prevents the use of the form for variations containing Line Extension when a single variation scope is included. In these cases the procedure is calculated as 'single' and it is not currently possible to edit this. In the next release of the form, this issue will be fixed and the tick box 'Including a line extension' will be always visible and it can be ticked to indicate a grouping with Line Extension application.

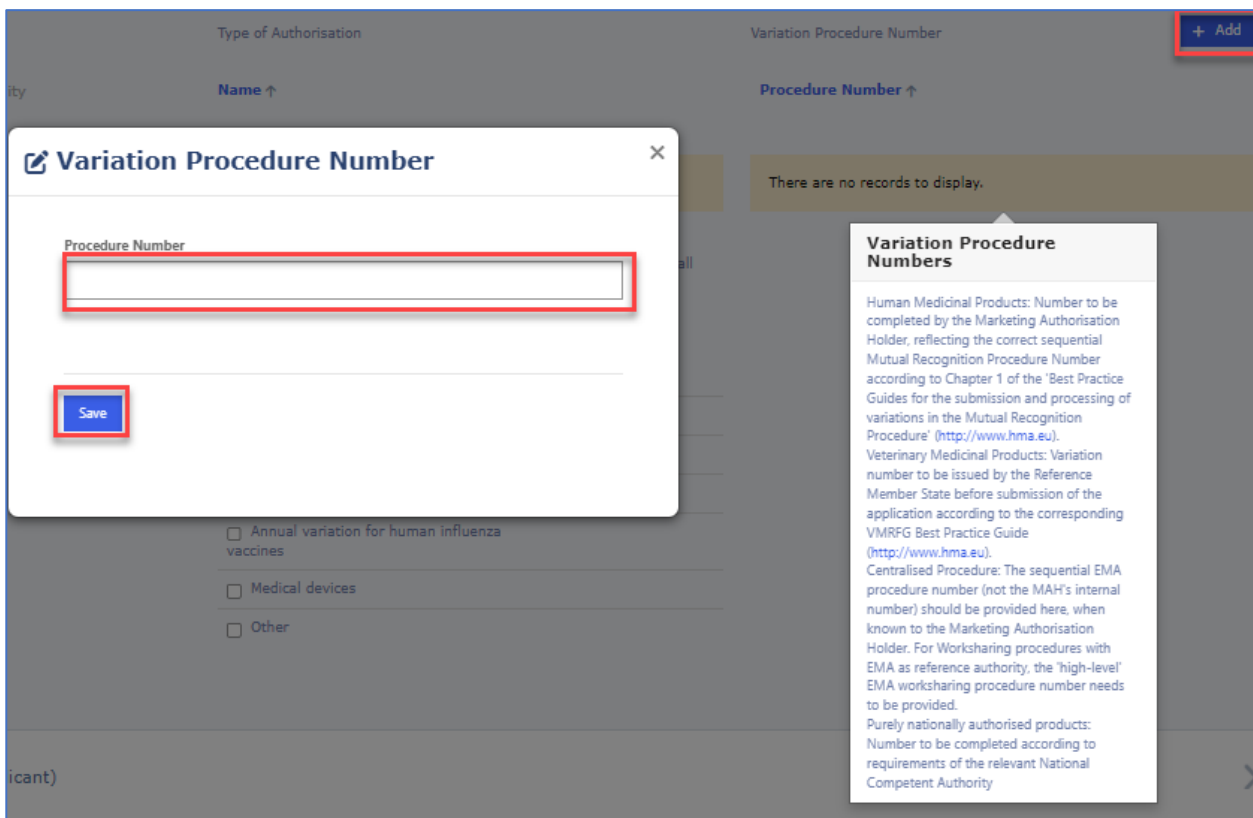
This limitation doesn't affect variations where there are more than one variation scopes included as the procedure is automatically calculated as grouping and the tick box to indicate line extension is visible.

- Type of Application; This field is auto calculated based on the Procedure Type and number of scopes selected. Please note that the terms 'Single variation' and 'Grouping of variations' as know in the pdf are slightly different in the web user interface (single regulatory activity and Grouped regulatory activity), however, the terms from the NTA form are still used in the pdf export.
- Worksharing; this field is auto calculated and is ticked by the system when more than one 'CAP Authorisation Products' i.e. products with different H/C/ 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 worksharing tickbox will be ticked.
- IG/Supergrouping; 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 autofilled 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 worksharing 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.



The screenshot shows the 'Variation Procedure Number' form. The main input field is labeled 'Procedure Number'. A red box highlights the 'Add' button in the top right corner. A sidebar on the right provides detailed instructions for different product types:

- Human Medicinal Products:** Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential Mutual Recognition Procedure Number according to Chapter 1 of the 'Best Practice Guides for the submission and processing of variations in the Mutual Recognition Procedure' (<http://www.hma.eu>).
- Veterinary Medicinal Products:** Variation number to be issued by the Reference Member State before submission of the application according to the corresponding VMRFG Best Practice Guide (<http://www.hma.eu>).
- Centralised Procedure:** The sequential EMA procedure number (not the MAH's internal number) should be provided here, when known to the Marketing Authorisation Holder. For Worksharing procedures with EMA as reference authority, the 'high-level' EMA worksharing procedure number needs to be provided.
- Purely nationally authorised products:** Number to be completed according to requirements of the relevant National Competent Authority.

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.

Name and Address of MA Holder (Applicant)

Reference MAH ⓘ

European Medicines Agency

Org ID
ORG-100013412

Address
Domenico Scarlattilaan 6
Amsterdam 1083 HS
Netherlands

LOC ID
LOC-100020264

Customer Account Number
—

Modified On
12/09/2022 19:09

Phone Number
Provide a telephone number

Email

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

Contact Person

Selected Contacts

+ Add

Member State	Title	First name	Surname	Telephone	E-Mail	Company ↑
There are no records to display.						

Add

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.

Create Application Contact

First name

Surname


Email

Phone
Provide a telephone number

Title

Member State

Company

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

Lookup records

Choose one record and click Select to continue

☒ **Organisation Name ↑**

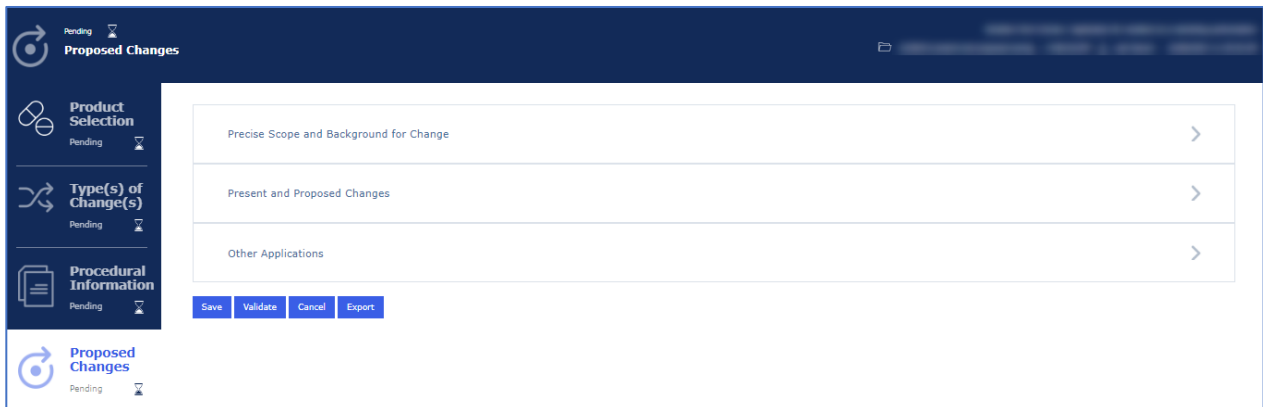
	Full address	Organisation id	Organisation Location
<input checked="" type="checkbox"/> Terveiden Ja Hyvinvoinnin Laitos	Mannerheimintie 166 00300 Helsinki Helsinki-Uusimaa Finland	ORG-100019555	LOC-100039037
<input type="checkbox"/> Terveiden Ja Hyvinvoinnin Laitos	PI 30 00271 Helsinki Finland	ORG-100019555	LOC-100039039

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.

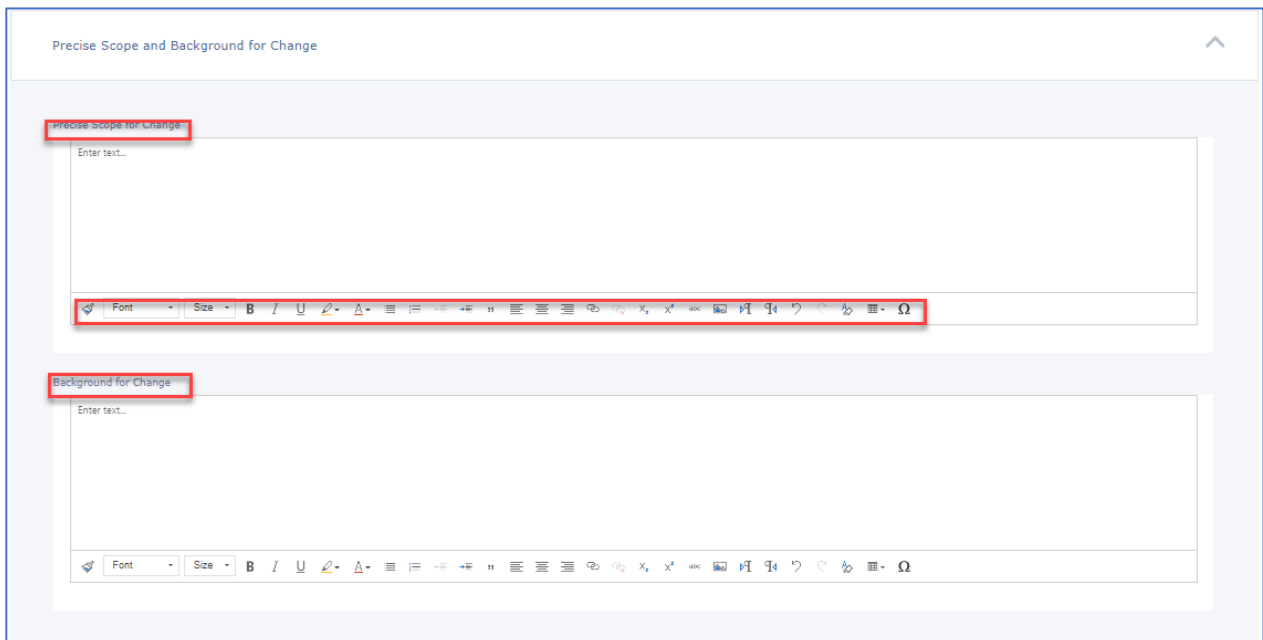


2.5.1. Precise Scope and Background for Change

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

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

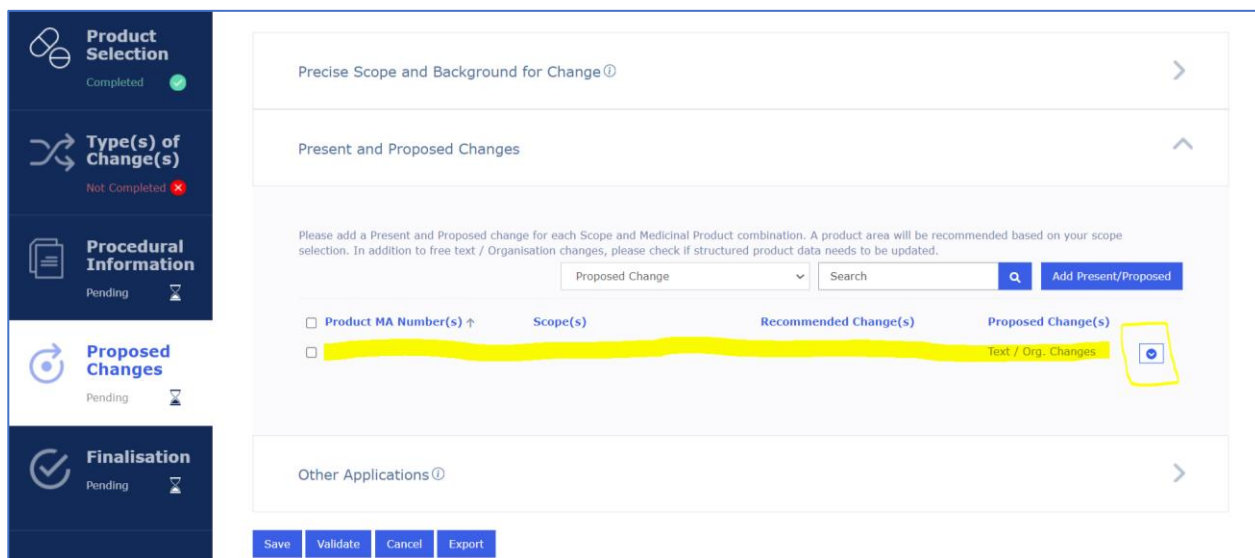
1. Access an existing or create a new Application Form. See sections 2.1.1, 2.1.2 and 2.1.3 for further details
2. Enter the Precise Scope for Change and Background for change in the corresponding free text fields. You can paste text into this field from another document (plain text only will be copied, 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.



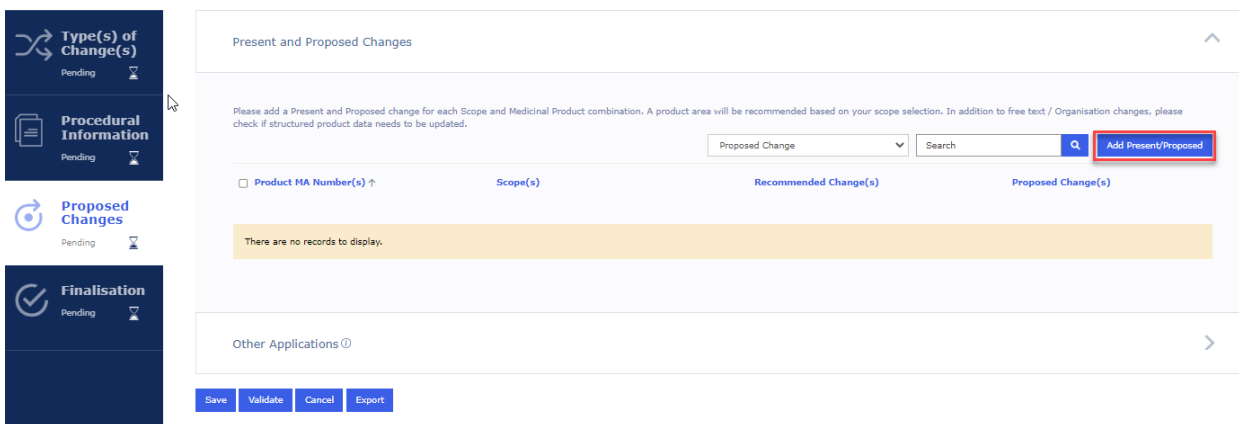
You can save your changes at any time, but please note that this will close the subsection which needs to be reopened to continue editing.

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.



2.5.2.1. Present and Proposed Text Changes



1. Click the click **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.

Proposed Changes > Present and Proposed Value(s) KP 18/09/22 Quality Grouping take2 / VAR/22/650 Last Saved : 18/09/20

Present and Proposed Value(s) Selected Scope(s) Selected Medicinal Product(s)

Present *

Enter text...

Font Size B U Color Align Indent Outdent Link Unlink Image Table Fullscreen

Proposed *

Enter text...

Font Size B U Color Align Indent Outdent Link Unlink Image Table Fullscreen

Organisation Details + Add

Organisation Not Selectable	Organisation Name (Present Organisation)	Organisation Location (Present Organisation)	Organisation ID (Present Organisation)	Full address (Present Organisation)	Parent Organisation ID (Present Organisation)	Modified On (Present Organisation)	Organisation Name (Proposed Organisation)	Organisation Location (Proposed Organisation)	Organisation ID (Proposed Organisation)	Full address (Proposed Organisation)	Parent Organisation ID (Proposed Organisation)	Modified On (Proposed Organisation)
No	European Medicines Agency	LOC-100010800	ORG-100006175	30 Churchill Place London E14 5EU United Kingdom	[INACTIVE] European Medicines Agency	17/07/2022 22:07	European Medicines Agency	LOC-100018793	ORG-100013412	Orlyplein 24 104 3 DP Amsterdam Netherlands	European Medicines Agency	12/09/2022 19:09
No	Austrian Agency For Health And Food Safety	LOC-100000001	ORG-100003912	Beethovenstrasse 6 8010 Graz Austria	Austrian Agency For Health And Food Safety	12/09/2022 14:09	Austrian Agency For Health And Food Safety	LOC-100000004	ORG-100003912	Traisengasse 5 Br igittenau 1200 Vienna Austria	Austrian Agency For Health And Food Safety	12/09/2022 14:09

☐ In case no OMS selection is done, I declare this change does not affect organisations unless the organisation is being deleted

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).

Present and Proposed Value(s) Selected Scope(s) Selected Medicinal Product(s)

Present *

Change 1 relates to the update of this and that.

Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and that.

Segoe UI 10 B U Color Align Indent Outdent Link Unlink Image Table Fullscreen

Proposed *

Change 1 relates to the update of this and that.

Change 1 relates to the update of this and that. ~~Change 1 relates to the update of this and that.~~ Change 1 relates to the update of this and that. Change 1 relates to the update of this and that.

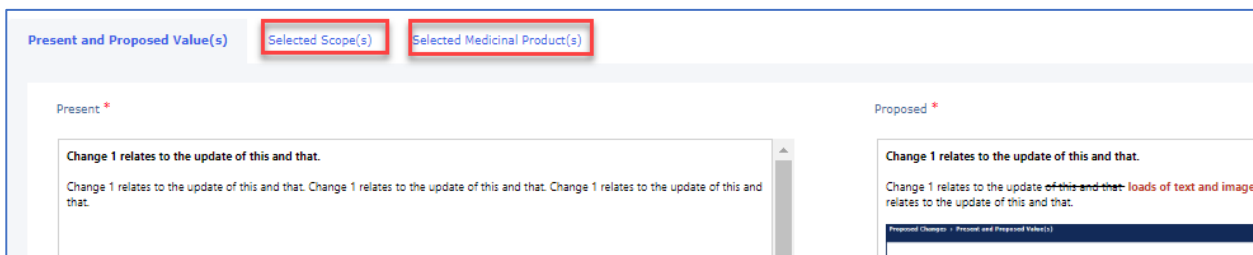
Segoe UI 10 B U Color Align Indent Outdent Link Unlink Image Table Fullscreen

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

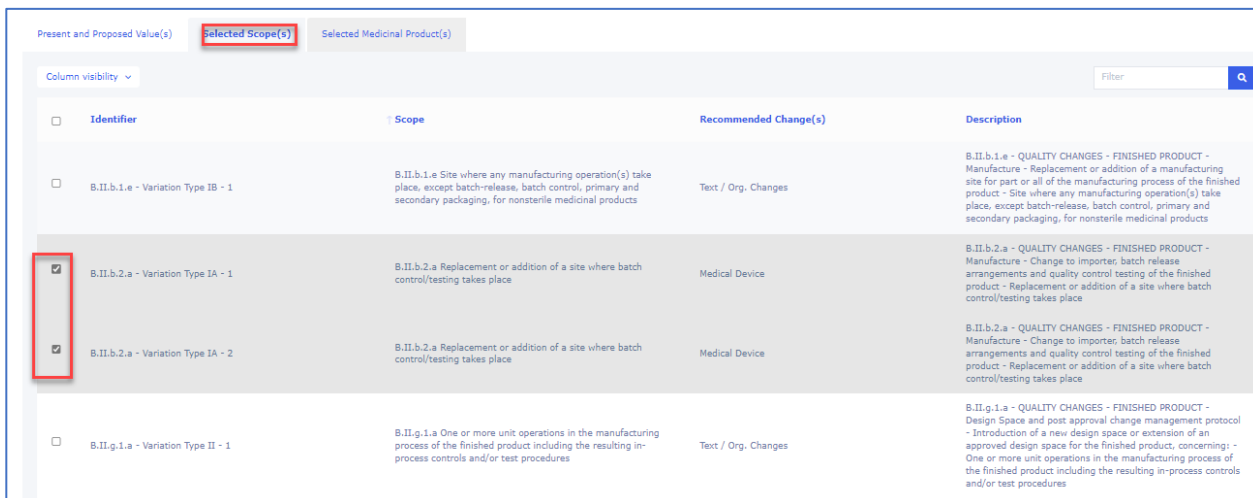
- Once you have added the editorial changes, relating to a specific scope(s) and packaged medicinal product(s) (i.e. presentation(s) you wish to link to together, please navigate using the tabs at the top of the section to link the scope and product. This is a mandatory step and the **selections of the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



- 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.



Identifier	Scope	Recommended Change(s)	Description
<input type="checkbox"/> B.II.b.1.e - Variation Type IB - 1	B.II.b.1.e Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products	Text / Org. Changes	B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products
<input checked="" type="checkbox"/> B.II.b.2.a - Variation Type IA - 1	B.II.b.2.a Replacement or addition of a site where batch control/testing takes place	Medical Device	B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
<input checked="" type="checkbox"/> B.II.b.2.a - Variation Type IA - 2	B.II.b.2.a Replacement or addition of a site where batch control/testing takes place	Medical Device	B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
<input type="checkbox"/> B.II.g.1.a - Variation Type II - 1	B.II.g.1.a One or more unit operations in the manufacturing process of the finished product including the resulting in-process controls and/or test procedures	Text / Org. Changes	B.II.g.1.a - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Introduction of a new design space or extension of an approved design space for the finished product, concerning - One or more unit operations in the manufacturing process of the finished product including the resulting in-process controls and/or test procedures

- 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

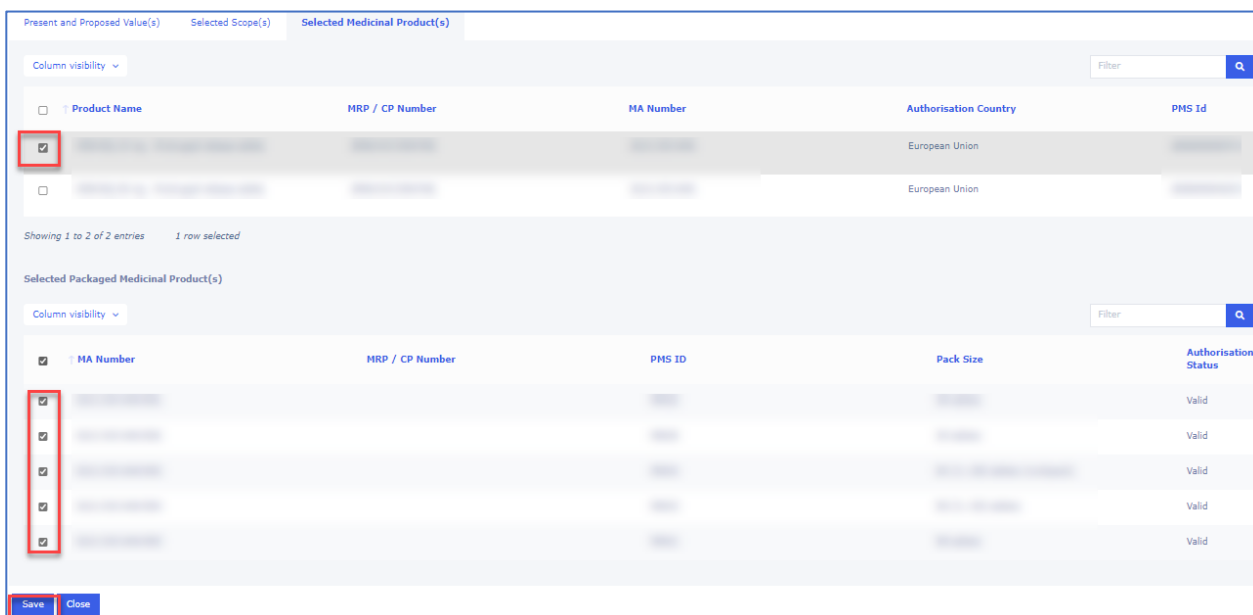
multiple changes/scopes that impact only part of the selected products, repeat this change to indicate the changes linked to those scopes.

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.



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.

Present and Proposed Changes

Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based on your scope selection. In addition to free text / Organisation changes, please check if structured product data needs to be updated.

Proposed Change Search

Product MA Number(s) ↑	Scope(s)	Recommended Change(s)	Proposed Change(s)
<input type="checkbox"/>	B.II.b.2.a - Variation Type IA - 1.B.II.b.2.a - Variation Type I A - 2	Medical Device	<input type="checkbox"/>

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.

5. 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.
6. If the change does not concerns 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 tickbox will prevent saving the text in the free text fields and combining the scope and presentation. It must be ticked first

Not Completed ✖

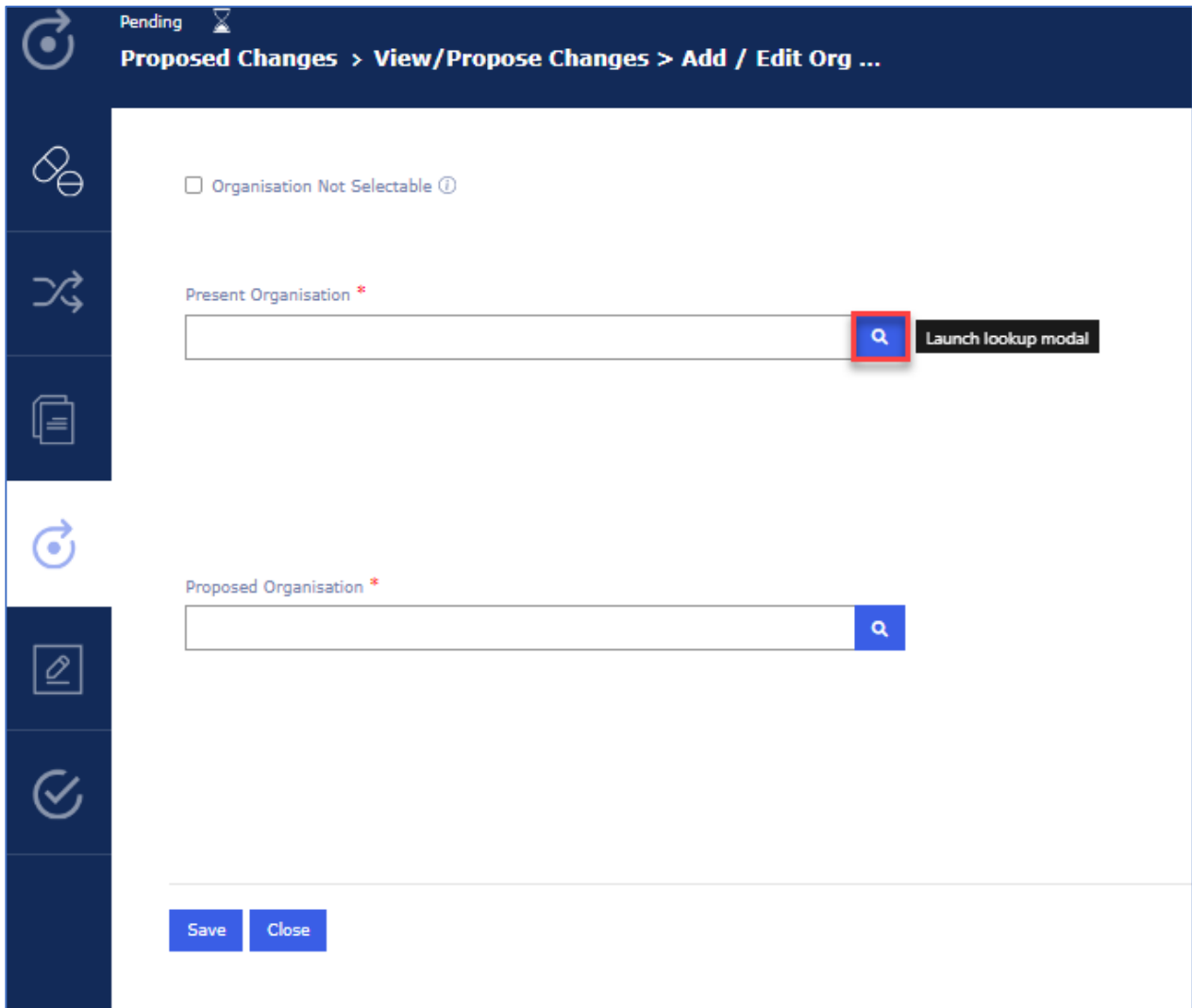
Proposed Changes > Present and Proposed Value(s)

Present and Proposed Value(s) Selected Scope(s) Selected Medicinal Product(s)

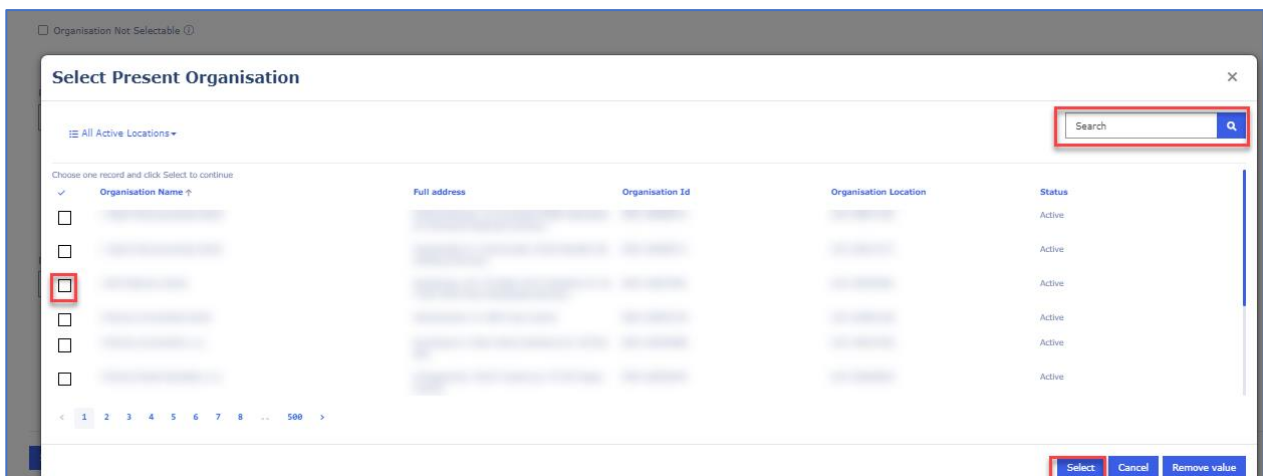
Present *

Enter text...

Font Size B I U



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



	Organisation Name	Full address	Organisation Id	Organisation Location	Status
<input checked="" type="checkbox"/>					Active
<input type="checkbox"/>					Active
<input type="checkbox"/>					Active
<input type="checkbox"/>					Active
<input type="checkbox"/>					Active
<input type="checkbox"/>					Active

9. 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.






Proposed Changes > View/Propose Changes > Add / Edit Org ...

☒ Organisation Not Selectable ⓘ

Organisation Not Selectable

The organisation is not selectable as 1) the organisation no longer exists, or 2) there is a change in organisation name which does not affect the address


Present Org

☒ Organisation Not Selectable ⓘ

Organisation Name * <input type="text"/>	City/Locality/Town/Village * <input type="text"/>
Address Line 1 * <input type="text"/>	Postcode <input type="text"/>
Address Line 2 <input type="text"/>	State <input type="text"/>
Address Line 3 <input type="text"/>	County <input type="text"/>
Address Line 4 <input type="text"/>	Country * <input type="text"/> <input type="button" value="Q"/>

- 10.** Add the details of the present organisation in the free text fields (only if the organisation is not available in OMS).
- 11.** 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.

Pending 

Proposed Changes > View/Propose Changes > Add / Edit Org ...


☒ Organisation Not Selectable ⓘ


Organisation Name *
 City/Locality/Town/Village *

Address Line 1 *
 Postcode

Address Line 2
 State

Address Line 3
 County

Address Line 4
 Country * 



Proposed Organisation * 

12. Select the organisation and press on the **Select** button.



13. When both organisations have been added, press the **Save** button to return to the Present and Proposed section to add the textual changes.

Proposed Changes > View/Propose Changes > Add / Edit Org ... KP 18/09/22 Q

☐ Organisation Not Selectable ⓘ

Present Organisation *  

Org ID	LOC ID
ORG-100006175	LOC-100010800
Address	
30 Churchill Place London E14 5EU United Kingdom	
Modified On	Status *
17/07/2022 22:07	Active

Proposed Organisation *  

Org ID	LOC ID
ORG-100013412	LOC-100018793
Address	
Orlyplein 24 Amsterdam 1043 DP Netherlands	
Modified On	
12/09/2022 19:09	

14. 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

2.5.2.4.2. Linking of the organisations to the text changes the Present and Proposed fields

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).

2.5.2.5. 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.

2.5.2.6. 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).

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

☒ Name

☒ Medical devices

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

Present and Proposed Changes

Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based on your scope selection. In addition to free text / Organisation changes, please check if structured product data needs to be updated.

☐ Product MA Number(s) ↑

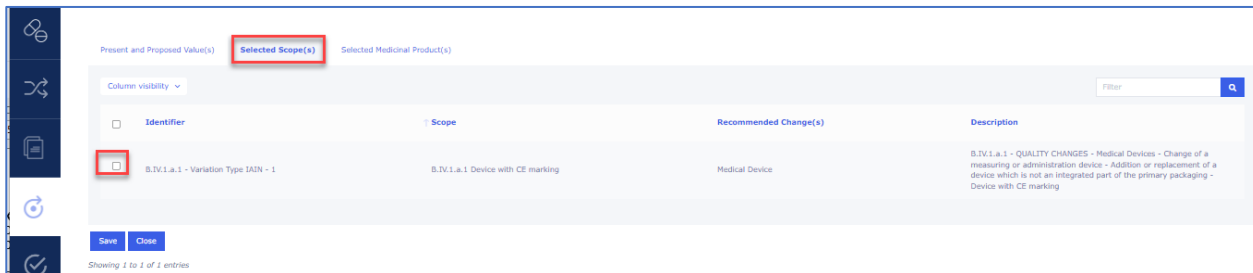
Scope(s)

Recommended Change(s)

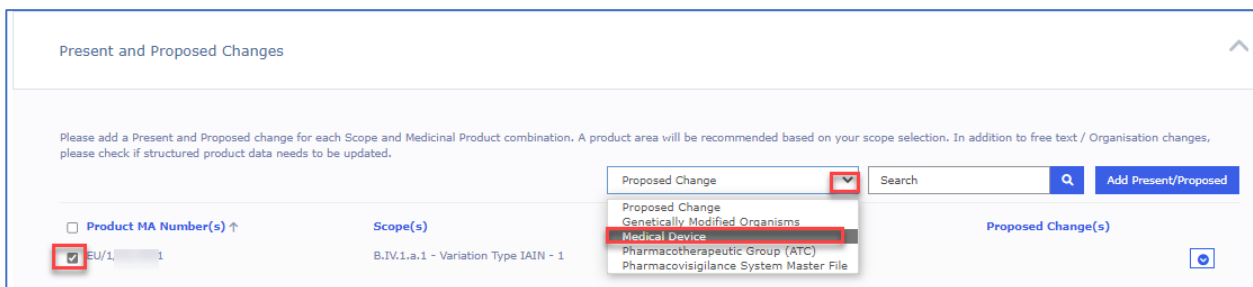
Proposed Change(s)

There are no records to display.

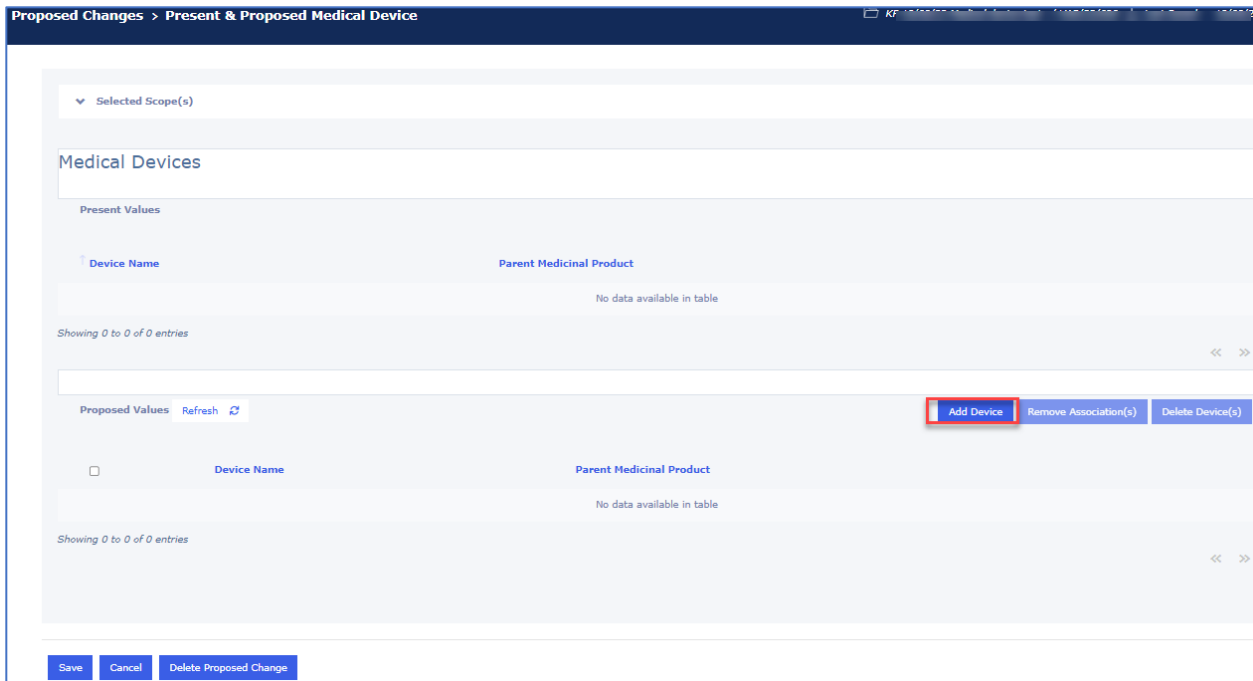
3. Select the scope and the medicinal product/presentations



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



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.



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.

Medical Device & Companion Diagnostic

Change to the design or intended purpose of the device component, or introduction of a new device / device constituent part	>
Device(s) identification and classification	>
Manufacturer of the device	>
Documentation to confirm compliance to the Medical Device Regulation (EU) 2017/745 and/or to the in vitro diagnostic Medical Device Regulation (EU) 2017/746	>
Notified Body (NB)	>

Save Cancel

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

Medical Device & Companion Diagnostic

Change to the design or intended purpose of the device component, or introduction of a new device / device constituent part

☐ a change to the design or intended purpose of a device component previously listed in the marketing authorisation of the medical product. Please explain the purposed changed in present/purposed section
☐ a new device introduced in the marketing authorisation of the medical product

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

Device(s) identification and classification

Name of the Device

Device Quantity

Classification *

Intended Purpose of the Device *

Type of Combination ⓘ *

Device Type *

Serial number / unique device identifier (UDI) or other indications necessary to delimit precisely the device incorporated, if applicable *

Brief Description of the Device *

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

Manufacturer of the device

Function *

Manufacturer *

Title *

First Name *

Last Name *

Telephone

E-Mail

10. Proceed to fill in the rest of the sections

Documentation to confirm compliance to the Medical Device Regulation (EU) 2017/745 and/or to the in vitro diagnostic Medical Device Regulation (EU) 2017/746

Does this application include a Manufacturer's EU declaration of conformity, an EU certificate issued by a Notified Body or a Notified Body opinion, if applicable?

Please note, the above mentioned documents (as applicable) should be provided in module 3.2.R of the EU-CTD.

11. Notified body is also now selected from OMS

Notified Body (NB)

Notified Body Number *

Name of the Notified Body *

Title *

First Name *

Last Name *

Telephone

E-Mail

2.5.2.7. 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 tickbox, 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**.

Present and Proposed Changes

Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based on your scope selection. In addition to free text / Organisation changes, please check if structured product data needs to be updated.

☐ Product MA Number(s) ↑

☒ 1

Scope(s)

B.IV.1.a.1 - Variation Type IAIN - 1

Proposed Change

Proposed Change
 Genetically Modified Organisms
 Medical Device
Pharmacotheapeutic Group (ATC)
 Pharmacovigilance System Master File

Search

Proposed Change(s)

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

Proposed Changes > Present & Proposed Pharmacotherapeuti...

KP 19/09/22 Medical device test / VAR/22/698 Last Saved : 19/09/202

Selected Scope(s)

Pharmacotheapeutic Group (ATC)

Present Values

MA number	Product Name
EU/1/21/1531	Evrysdi 0.75 mg/ml - Powder for oral solution

Showing 1 to 1 of 1 entries

Proposed Values

ATC Code ↑

Application for ATC code has been made

There are no records to display.

Save Cancel Delete Proposed Change

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

Select ATC Code

FHIR Product ATC Code

ATC Code

☐ If no ATC code has been assigned, please indicate if an application for ATC code has been made

- Click on the **Submit** 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

2.5.2.8. Pharmacovigilance System Master File

1. Select the relevant product by using the tickbox 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.

Pharmacovigilance system master file

Present Values

MA Number	Product Name	PSMF Code	PSMF Organization	The Pharmacovigilance system master file location has been registered in Article 57 database

Showing 1 to 1 of 1 entries

Proposed Values


PSMF Organisation *

PSMF Code *

☐ The Pharmacovigilance system master file location has been registered in Article 57 database

Note: For Risk Management Plan, see module 1, 1.8.2.6 For the purposes of this application form, a Qualified person Responsible for Pharmacovigilance 'resides' in the place where he/she makes his/her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.

[Save](#) [Delete Proposed Change](#) [Cancel](#)

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

2.5.2.9. Genetically Modified Organisms

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

Selected Scope(s)

Genetically Modified Organisms

Present Values

MA Number	Product Name	Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?	If yes, does the product comply with Directive 2001/18/EC?
		No	

Showing 1 to 1 of 1 entries

Proposed Values

Does the medicinal product contain GMOs? *

Yes

Does the product comply with Directive 2001/18/EC? *

Yes

☐ Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 5.13)

Save Cancel Delete Proposed Change

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

2.5.3. Other applications

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

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

Other Applications

Select EMA Procedure Add

Procedure Number ↑

There are no records to display.

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

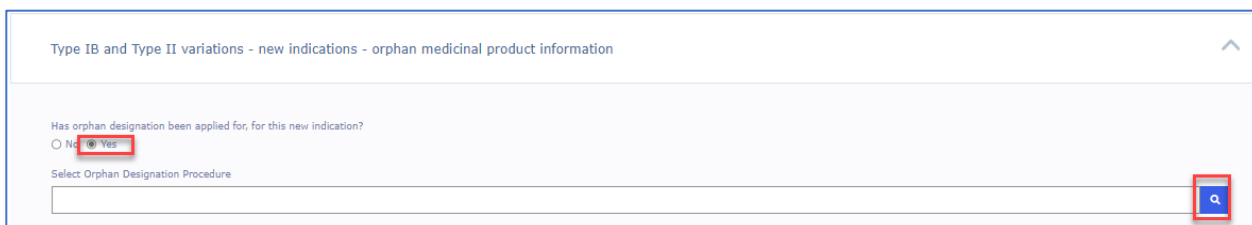
a delay in calculating this information based on the procedure type and the product and it can take several minutes before these sections appear in the form.



The screenshot shows a sidebar on the left with three sections: 'Type(s) of Change(s)' (Completed), 'Procedural Information' (Completed), and 'Proposed Changes' (Completed). The main area displays a list of variation types: 'Type IB and Type II variations - new indications - orphan medicinal product information', 'Information relating to orphan market exclusivity', 'Type IB and Type II variations - Paediatric Requirements', and 'Type II variations - Extended data exclusivity / market protection'. At the bottom, there are buttons for 'Save', 'Validate', 'Cancel', and 'Export'.

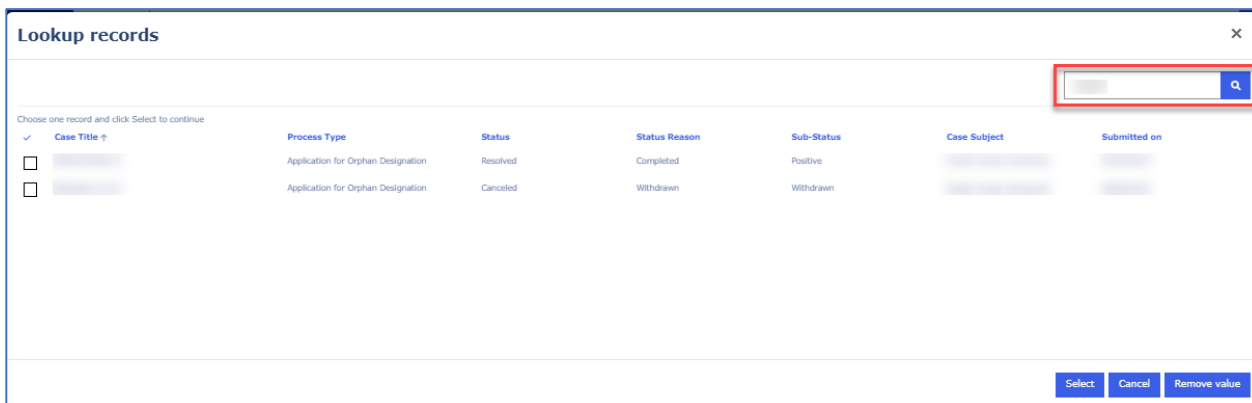
2.6.1. Type IB and Type II Variations – new indications – orphan medicinal product information

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



The screenshot shows the 'Type IB and Type II variations - new indications - orphan medicinal product information' section. It contains a question: 'Has orphan designation been applied for, for this new indication?' with radio buttons for 'No' and 'Yes'. Below this is a text field labeled 'Select Orphan Designation Procedure' with a magnifying glass icon on the right.

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



The screenshot shows a 'Lookup records' window. It has a search bar at the top right. Below the search bar is a table with the following columns: 'Case Title', 'Process Type', 'Status', 'Status Reason', 'Sub-Status', 'Case Subject', and 'Submitted on'. The table contains two rows of data. At the bottom right, there are buttons for 'Select', 'Cancel', and 'Remove value'.

Case Title	Process Type	Status	Status Reason	Sub-Status	Case Subject	Submitted on
	Application for Orphan Designation	Resolved	Completed	Positive		
	Application for Orphan Designation	Cancelled	Withdrawn	Withdrawn		

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

Has orphan designation been applied for, for this new indication?
☐ No ☒ Yes

Select Orphan Designation Procedure
 EMA/OD/050/15

Orphan designation procedure status
☐ Pending ☒ Orphan Designation Granted ☐ Orphan Designation Refused ☐ Orphan Designation Withdrawn

Orphan designation date
 10/08/2015

Based on the criterion of "significant benefit":
☐ No ☒ Yes

Number in the Community Register of Orphan Medicinal Products
 EU/3/15/1532

☐ Attach copy of the Designation Decision

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.

Type IB and Type II variations - Paediatric Requirements

Applicable Paediatric Regulation

- ☒ Article 8 of Paediatric Regulation applies to this variation application since.
- ☐ Article 8 of the paediatric regulation does not apply to this application since.
- ☐ This application relates to a new indication for a paediatric use marketing authorisation (PUMA).
- ☐ This application relates to paediatric studies included in a paediatric investigation plan.
- ☐ This application relates to paediatric studies submitted according to Article 45 or 46 of the paediatric regulation.

Article 8 Procedure Type

- ☐ This application relates to a previous/ongoing/parallel procedure which triggered Article 8 requirement.
- ☒ This application relates to a new indication for an authorised medicinal product which:

Article 8 New Indication

- ☐ is protected by a supplementary protection certificate under Regulation (EC) No 469/2009.
- ☐ is protected by a patent which qualifies for the granting of the supplementary protection certificate.
- ☒ This application relates to paediatric studies included in a paediatric investigation plan
- ☐ This application relates to paediatric studies submitted according to Article 45 or 46 of the paediatric regulation

+ Add

Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision	Agreed scope ↑	Agreed condition/indication
There are no records to display.					

(Note: a copy of the PIP/Product-Specific Waiver decision including the paediatric Committee (PDCO) opinion and the Summary Report, is to be included in Module 1.10)

Has this application been subject

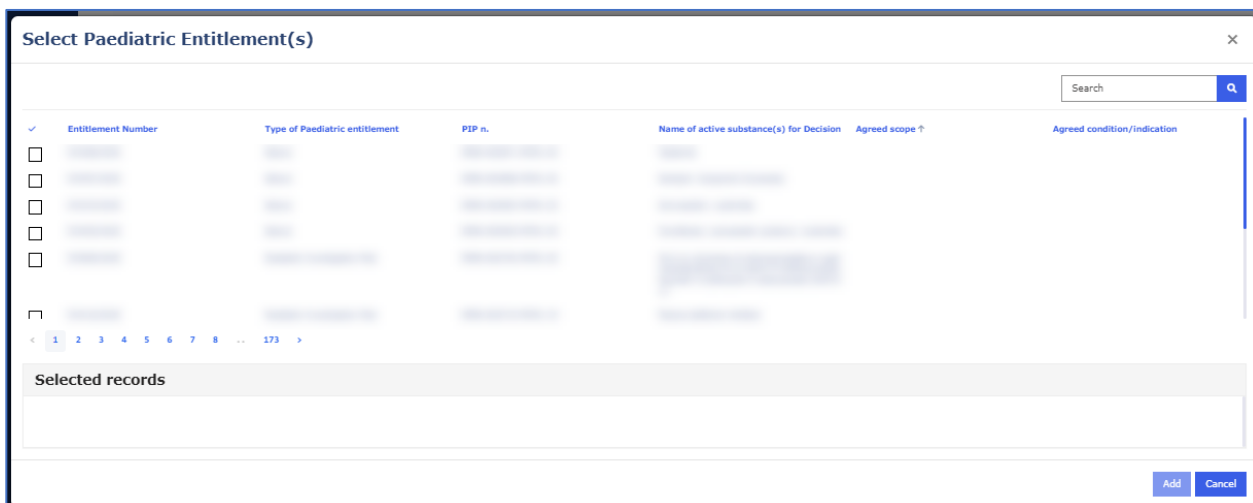
Has this application been subject to PIP compliance verification?
☐ No ☒ Yes

+ Add

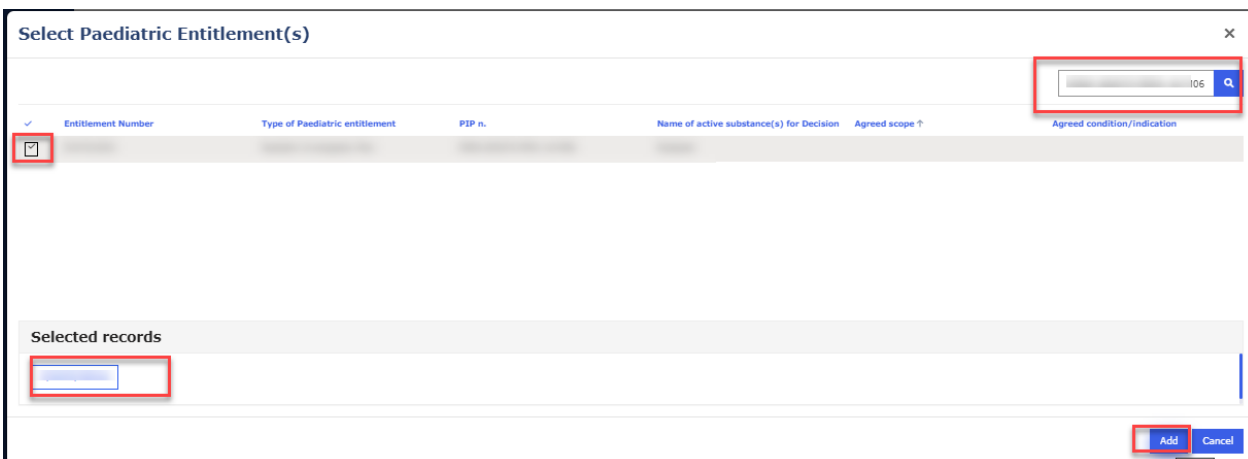
The compliance document reference ↑

There are no records to display.

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



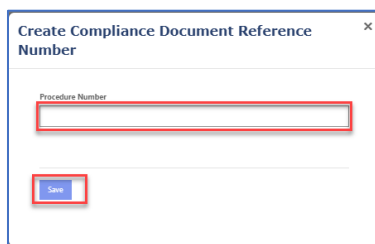
5. Add the entitlement



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



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



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

Type II variations - Extended data exclusivity / market protection

Extended data exclusivity / market protection

☐ Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 726/2004 (one year of market protection for a new indication).
☐ Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication).
☐ Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification).
☒ Not applicable

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).

Pending
Finalisation

Product Selection
Pending

Type(s) of Change(s)
Pending

Procedural Information
Pending

Proposed Changes
Pending

Finalisation
Pending

Annexed documents (where appropriate) >

Declaration >

Proof of payment >

Signatories >

Save Validate Cancel Export Finalise

2.7.1. Annexed documents (where appropriate)

Annexed documents (where appropriate)

The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable.

☐ Mock ups
☐ Specimens
☐ Summary of Product Characteristics
☐ Labelling
☐ List of all authorised presentations (Annex A)
☐ Package Leaflet
☐ Restrictions posed by Member States (Annex 127a)
☐ Annex II

2.7.2. Declaration of the applicant

Declaration of the applicant

I hereby submit a notification/application for the above Marketing Authorisation(s) to be varied in accordance with the proposals given above. I declare that (Please tick appropriate declarations)

☐ Where applicable, national fees have been prepaid or will be paid in accordance with national requirements;
☐ For type IA notifications: the required documents as specified for the changes concerned have been submitted;
☐ This notification/application has been submitted simultaneously in RMS and all CMSs (for products within the Mutual Recognition Procedure and worksharing) or both to EMA and (Co-)Rapporteur (for products within the Centralised Procedure) or, in case of worksharing involving the EMA, to the relevant National Competent Authorities and/or RMS/ CMS (as applicable) and the EMA;
☐ * There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);
☐ For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.
☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled;

Change(s) will be implemented from: *

Next production run/next printing: ☐

Changes implementation date:

Changes implementation comment:

2.7.3. Proof of Payment

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

Proof of payment

Have all relevant fees been prepaid to competent authorities? ⓘ

☒ No ☐ Yes (for the fees paid, attach proof of payment in Annex)

Customer Purchase Order / Reference Number	Address / Billing address ↑	Customer Account Number	Full Address	Telephone	E-Mail
	European Medicines Agency		Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands		

2.7.4. Signatories

Signatories

Main Signatory	Additional Signatory
First Name * <input type="text"/>	First Name <input type="text"/>
Surname * <input type="text"/>	Surname <input type="text"/>
Status(Job Title) * <input type="text"/>	Status(Job Title) <input type="text"/>
Date * <input type="text" value="dd/mm/yyyy"/> ⓘ	Date <input type="text" value="dd/mm/yyyy"/> ⓘ

☐ For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the designated contacts as specified in section 2.4.3 in Part IA/Module 1 Application Form for each of the MAs concerned.

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.

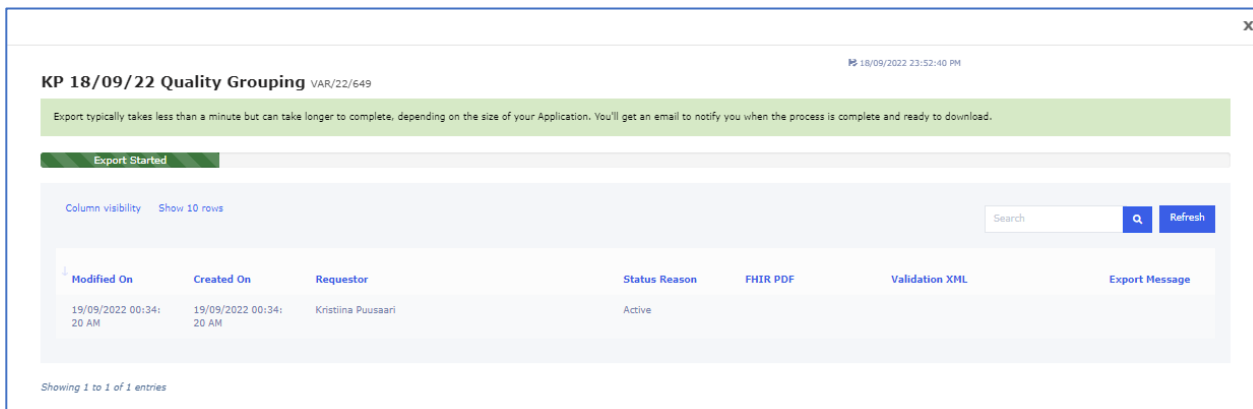
The pdf eAF exported from the web user interface cannot be edited outside the PLM Portal. The forms cannot be signed in the web user interface. If the user wishes to include a signature in exported pdf, this should be done using any external signature tool.

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



KP 18/09/22 Quality Grouping VAR/22/649

Export typically takes less than a minute but can take longer to complete, depending on the size of your Application. You'll get an email to notify you when the process is complete and ready to download.

Export Started

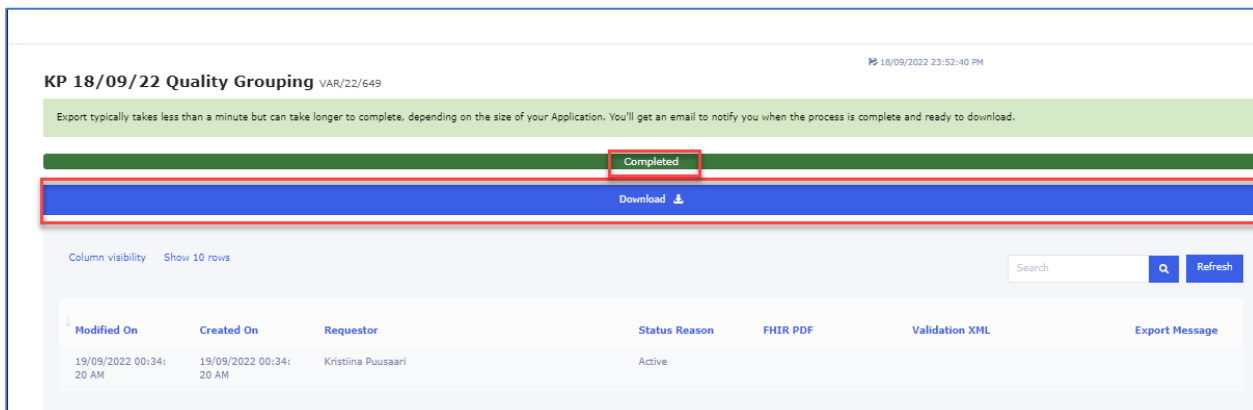
Column visibility Show 10 rows

Search Refresh

Modified On	Created On	Requestor	Status Reason	FHIR PDF	Validation XML	Export Message
19/09/2022 00:34:20 AM	19/09/2022 00:34:20 AM	Kristina Puusaari	Active			

Showing 1 to 1 of 1 entries

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



KP 18/09/22 Quality Grouping VAR/22/649

Export typically takes less than a minute but can take longer to complete, depending on the size of your Application. You'll get an email to notify you when the process is complete and ready to download.

Completed

Download

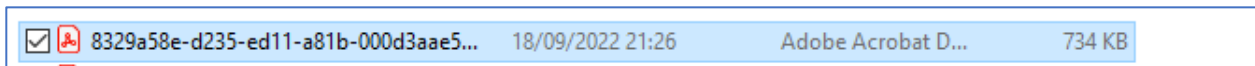
Column visibility Show 10 rows

Search Refresh

Modified On	Created On	Requestor	Status Reason	FHIR PDF	Validation XML	Export Message
19/09/2022 00:34:20 AM	19/09/2022 00:34:20 AM	Kristina Puusaari	Active			

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.

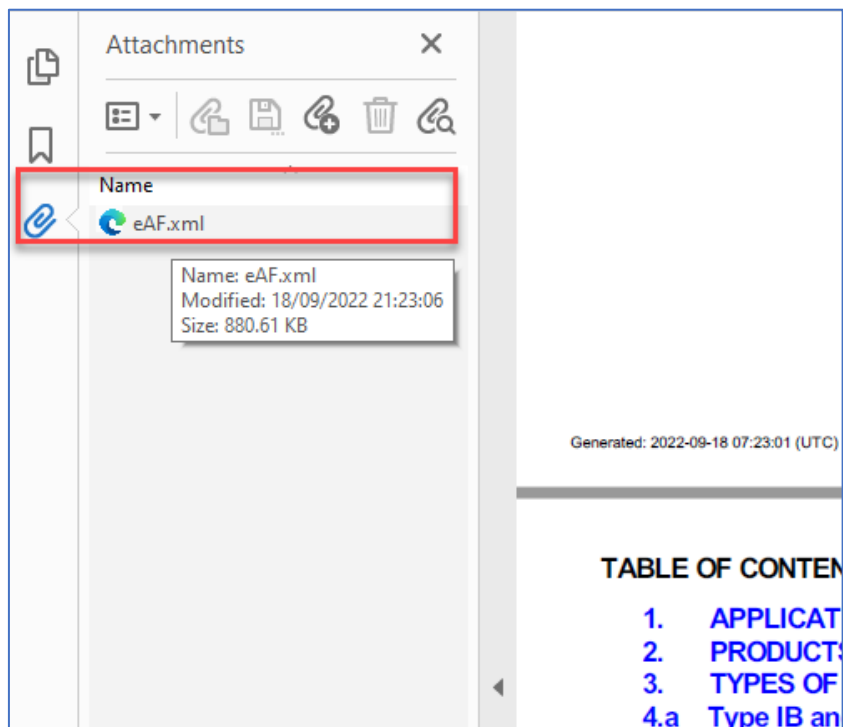


8329a58e-d235-ed11-a81b-000d3aae5... 18/09/2022 21:26 Adobe Acrobat D... 734 KB

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.



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/90000000001"/>
                  <code value="90000000004"/>
                  <display value="Not Applicable"/>
                </coding>
              </type>
              <valueBoolean value="false"/>
            </input>
          </Task>
        </contained>
      </resource>
    </entry>
  </Bundle>

```

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 eAF Forum*

The **eAF Forum** is a public platform where users (primarily applicants) can stay up to date on the latest eAF news (e.g., new eAF 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.

4.2. *The Service Desk*

For **technical support** with EMA's IT systems, please use 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.

To raise an issue using the EMA Service Desk tool; please select the option [Report an issue](#) and select the service PLM Portal – eAF. For questions, please select the option [Ask a question](#)

Depending on the issue or question, you can select from different options;

- 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.

Report an Issue

Request assistance with an issue you are having.



Report an issue you are having regarding IT systems, applications or devices, by filling out the following form. Make sure to include as much detail as possible. An incident record will be created and managed through to successful resolution. You will also be notified of progress.

Examples:

- Report an issue with business applications / software / network connectivity
- Issues with audio visual meeting room equipment (e.g. projectors, voting system or audio quality)

* Indicates required

* Raise this request on behalf of

* Service

* Service Offering


PLM portal – eAF FHIR XML

PLM portal – eAF General

PLM portal – eAF PDF Export

PLM portal – eAF Web-form User Interface

* Urgency

 Add attachments