



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guide to navigation – March 2025 update

Product Lifecycle Management Portal – Human Variations eAF

CAPs and non-CAPs

Version 1.8

UPDATED DRAFT
including non-CAPS

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Acronym key and glossary terms

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

UPDATED DRAFT

1. Purpose and Context

IMPORTANT NOTE FOR USERS: The PLM Portal web-based eAF is now open for all types of variation applications for all products, including those authorised through purely national procedures (NP), mutual recognition procedure (MRP) and decentralised procedure (DCP). The MAHs are now invited to use the web based eAF for submissions to the NCAs from 11th February 2025.

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

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

If you are using the web based form and you have an issue, please report these through the service desk. In all other exploratory cases, please refrain from raising tickets on non-CAP issues/change requests through EMA's service desk to allow us concentrate on supporting ongoing production applications.

1.1. Purpose of this guide

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

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

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

1.2. Preliminary requirements

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

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

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



1.3. Supported Browsers

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

UPDATED DRAFT

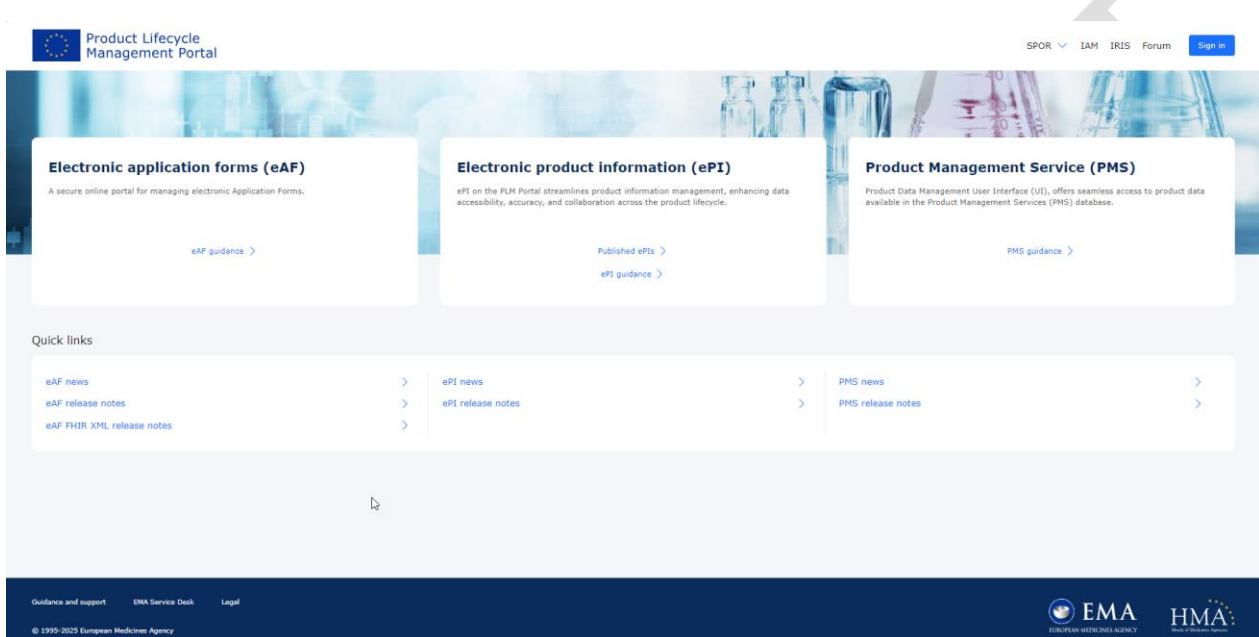
2. Navigation through the PLM Portal - eAF

2.1. Creating an application form

2.1.1. How to access the PLM Portal eAF

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

Figure 1. Sign-in

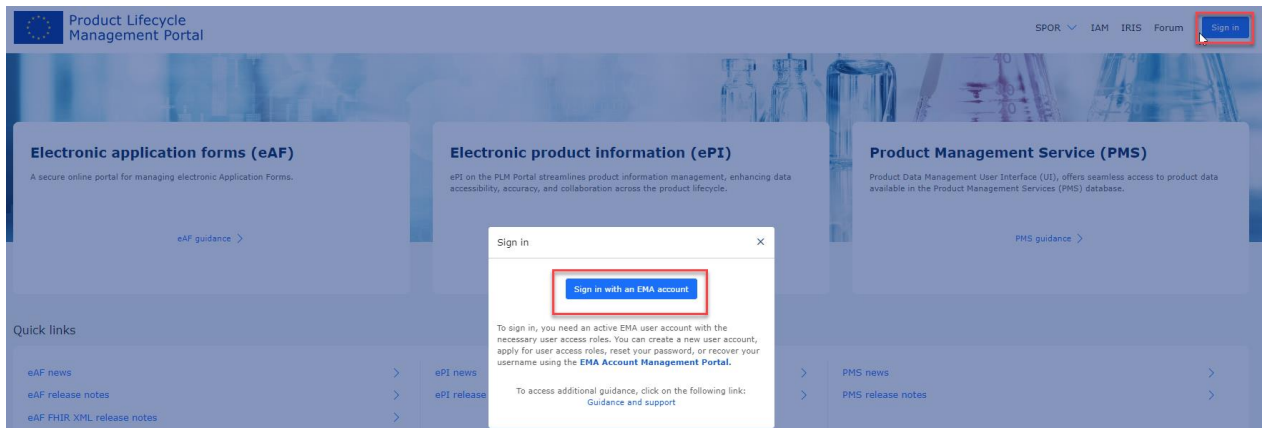


2.1.2. How to create a new electronic Application Form

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

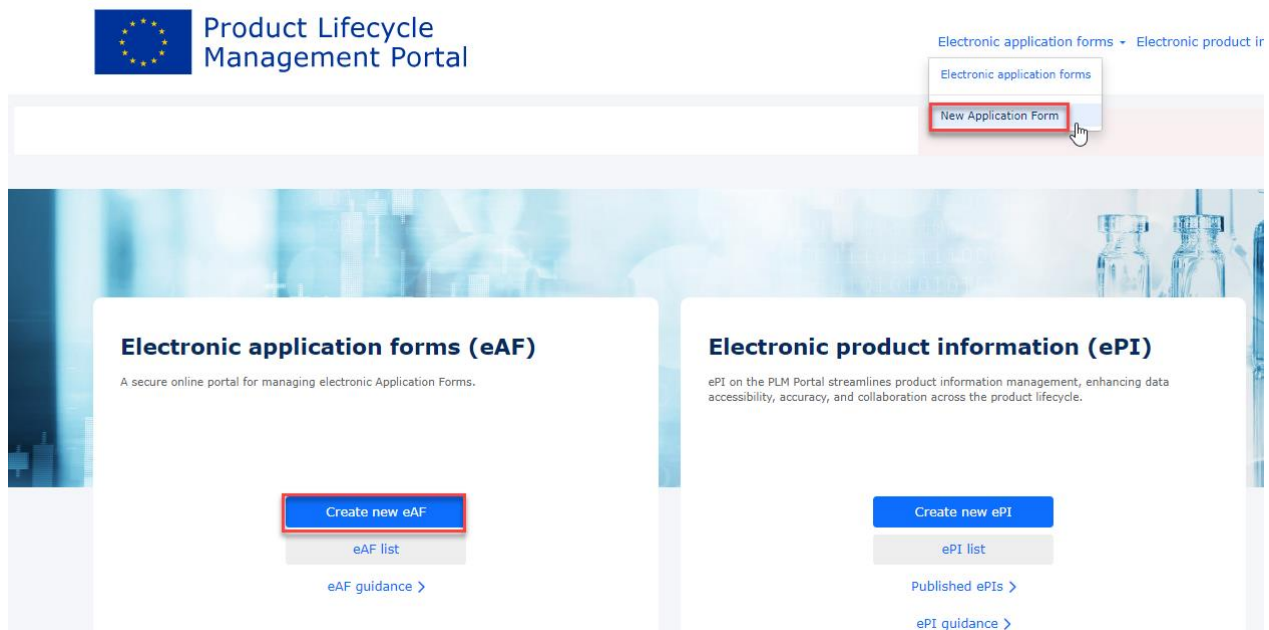
1. Sign into the PLM Portal – eAF

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



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

Figure 2. New Application Form



3. Click on [Create new eAF/New Application Form](#)

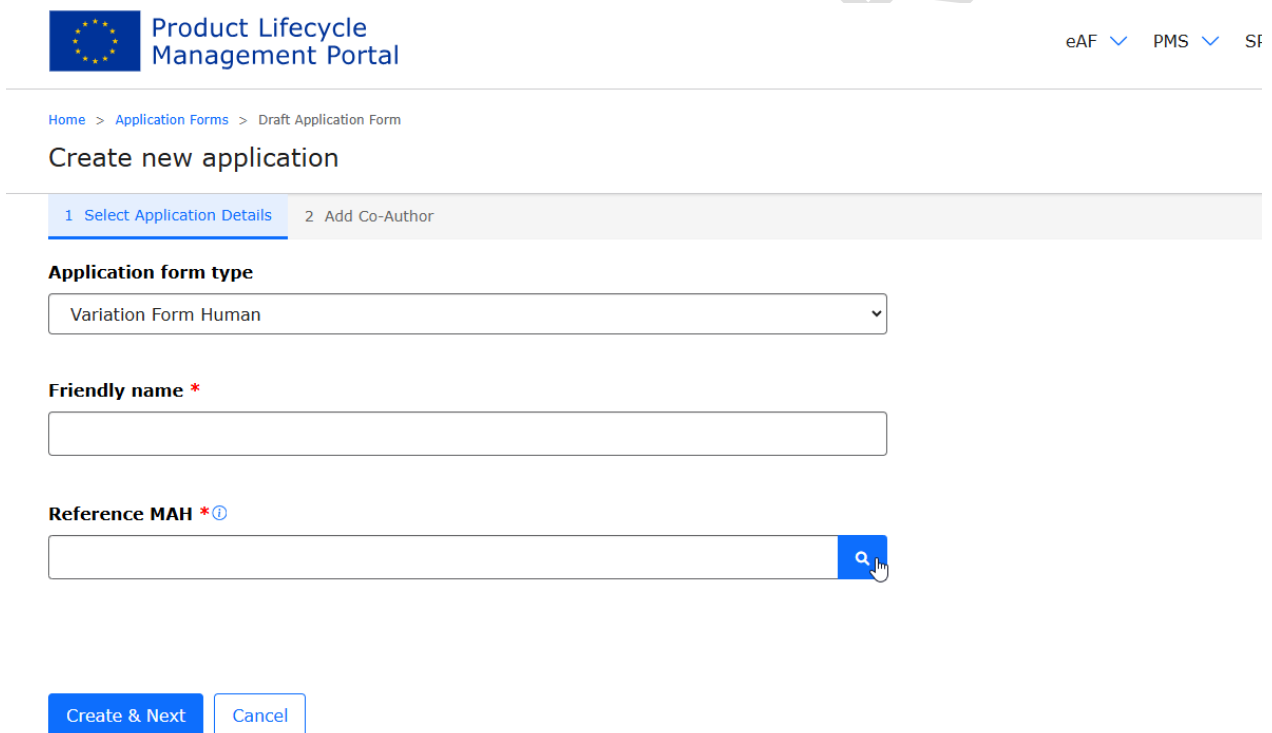
You will be prompted with the *Draft Application Form* page. In order to complete the Application Form creation procedure, and be able to go back to that Application Form at any point in time in the future, you must complete:

- The step 1. Select [Application Details](#) and,
- Optionally, the step [2. Add Co-Author](#).

In the 1. *Select Application Details* screen:

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

Figure 3. Application Form Type



The screenshot shows the 'Product Lifecycle Management Portal' interface. At the top right, there are navigation links for 'eAF', 'PMS', and 'SF'. The breadcrumb trail is 'Home > Application Forms > Draft Application Form'. The main heading is 'Create new application'. Below this, there are two steps: '1 Select Application Details' (active) and '2 Add Co-Author'. The 'Application form type' dropdown menu is set to 'Variation Form Human'. There is an empty text input field for 'Friendly name *' and another for 'Reference MAH *' with a search icon on the right. At the bottom, there are two buttons: 'Create & Next' and 'Cancel'.

- Add a **Friendly Name** (e.g.: *Productname Type II quality*) – ideally this name should be **meaningful** and help you to identify the application form from a potentially large list of other application forms. For example the product name and procedure number, if known, might be helpful attributes. Try and make it meaningful so that you and/or colleague can find your variation form again if needed.

Figure 4. Application Details

Create new application

1 Select Application Details 2 Add Co-Author

Application form type

Variation Form Human

Friendly name *

SuperPill 50mg - change of manufacturer of the primary packaging

Reference MAH * ⓘ

- Please note that it is now possible to change originally given Friendly name.
 - To change or update the Friendly name, please select the option '**Rename application form**' from the application list right hand menu

Home > Application Forms

Application Forms + New application

Draft Deactivated Completed All Column visibility ↓

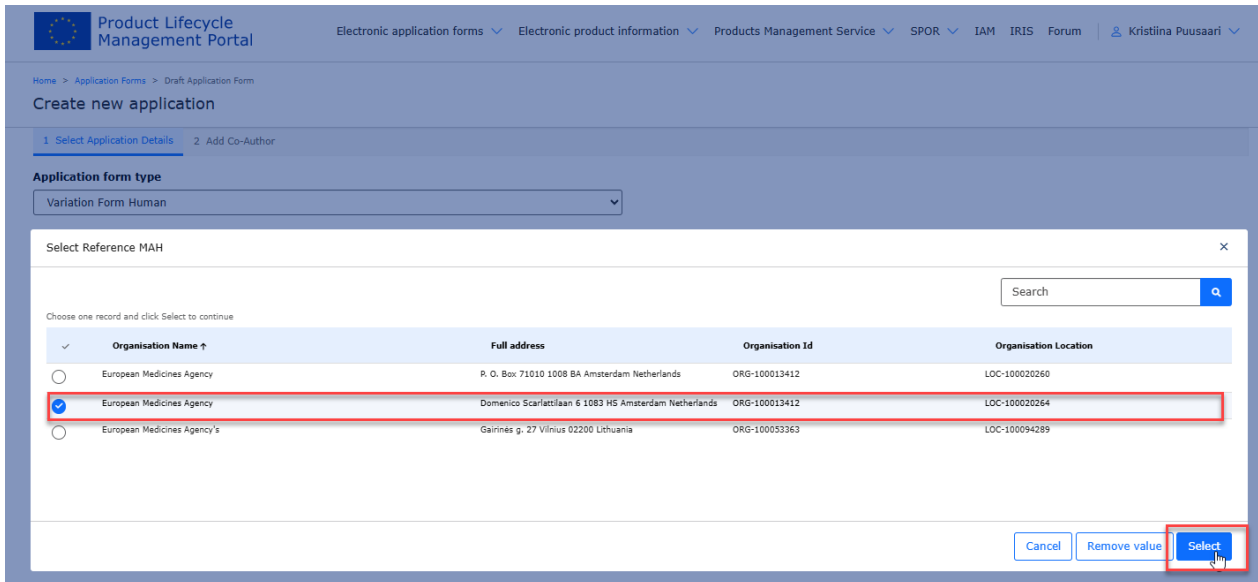
Application form ID	Friendly name	Application form type	Reference MAH	Created by	Created on	Last modified by	Last modified on	Status	Actions
VAR/25/92		Variation Form Human		Kristina Sheahan	08/01/2025 09:02	Kristina Sheahan	08/01/2025 17:01	Draft	View/Manage Co-authors
VAR/25/77		Variation Form Human	European Medicines Agency	Kristina Puusaari	07/01/2025 15:45	Kristina Puusaari	07/01/2025 15:45		Deactivate Application Form
VAR/25/34		Variation Form Human		Kristina Sheahan	06/01/2025 10:42	Kristina Sheahan	07/01/2025 09:09		Exports
VAR/25/41		Variation Form Human	European Medicines Agency	Kristina Puusaari	06/01/2025 16:23	Kristina Puusaari	06/01/2025 17:11	Draft	Rename Application Form

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

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

It is currently not possible to filter 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.

Figure 5. Reference MAH



Product Lifecycle Management Portal

Electronic application forms | Electronic product information | Products Management Service | SPOR | IAM | IRIS | Forum | Kristiina Puusaari

Home > Application Forms > Draft Application Form

Create new application

1 Select Application Details | 2 Add Co-Author

Application form type: Variation Form Human

Select Reference MAH

Search

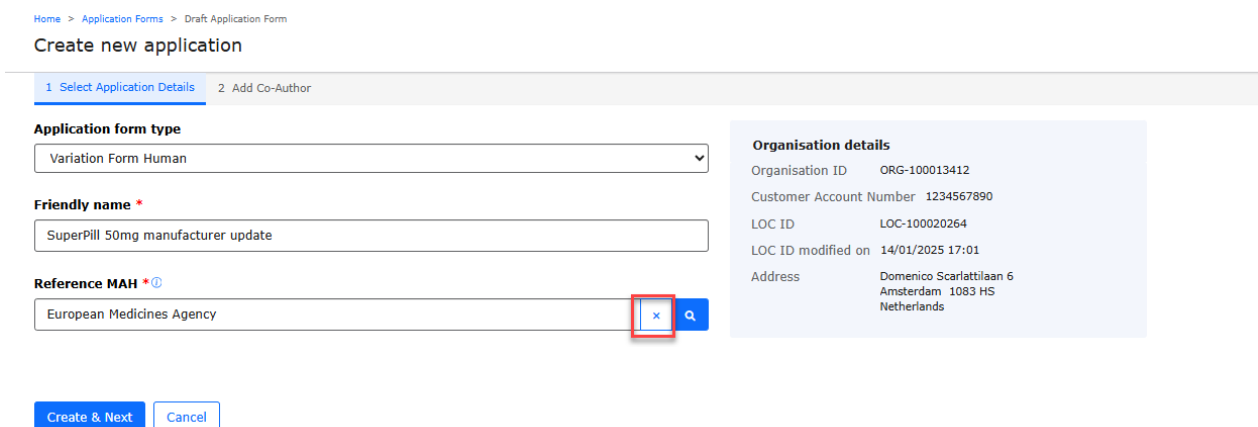
Choose one record and click Select to continue

Organisation Name	Full address	Organisation Id	Organisation Location
<input type="radio"/> European Medicines Agency	P. O. Box 71010 1008 BA Amsterdam Netherlands	ORG-100013412	LOC-100020260
<input checked="" type="radio"/> European Medicines Agency	Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands	ORG-100013412	LOC-100020264
<input type="radio"/> European Medicines Agency's	Gainines g. 27 Vilnius 02200 Lithuania	ORG-100053363	LOC-100094289

Cancel Remove value **Select**

- Click **Select** to select the MAH from the list. Depending on your role and affiliation, you may only have 1 or more options to select the MAH from. After you have selected the MAH, it is still possible to change it at this point if you realise it is not the correct organisation/location. You can remove the organisation by clicking the **X** next to the magnifying glass. At this point, you can select or perform a search/filtering as many times as needed.

Figure 6. Create & Next Button



Home > Application Forms > Draft Application Form

Create new application

1 Select Application Details | 2 Add Co-Author

Application form type: Variation Form Human

Friendly name *: SuperPill 50mg manufacturer update

Reference MAH *: European Medicines Agency

Organisation details

Organisation ID: ORG-100013412
Customer Account Number: 1234567890
LOC ID: LOC-100020264
LOC ID modified on: 14/01/2025 17:01
Address: Domenico Scarlattilaan 6, Amsterdam 1083 HS, Netherlands

Create & Next Cancel

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

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

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

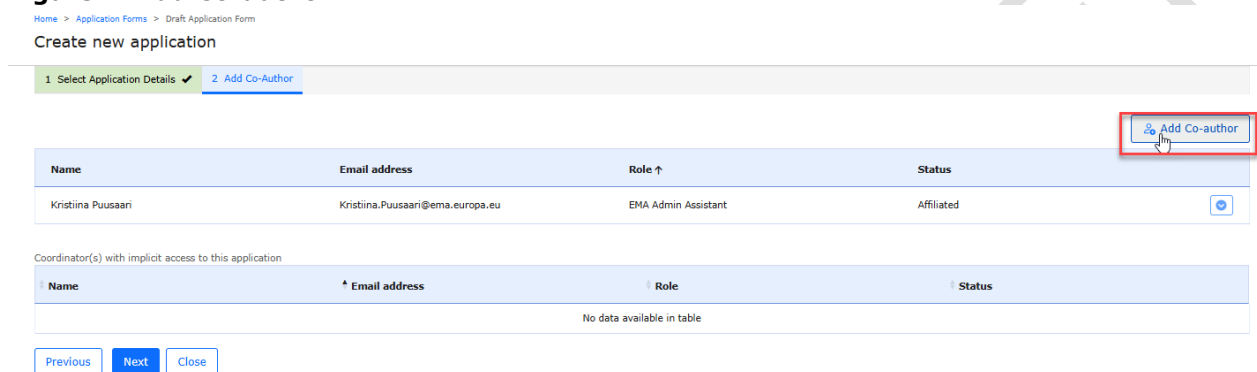
Click on the **Add Co-author** button – to add co-authors to that Application Form

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

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

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

Figure 7. Add Co-author



Home > Application Forms > Draft Application Form
Create new application

1 Select Application Details ✓ 2 Add Co-Author

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

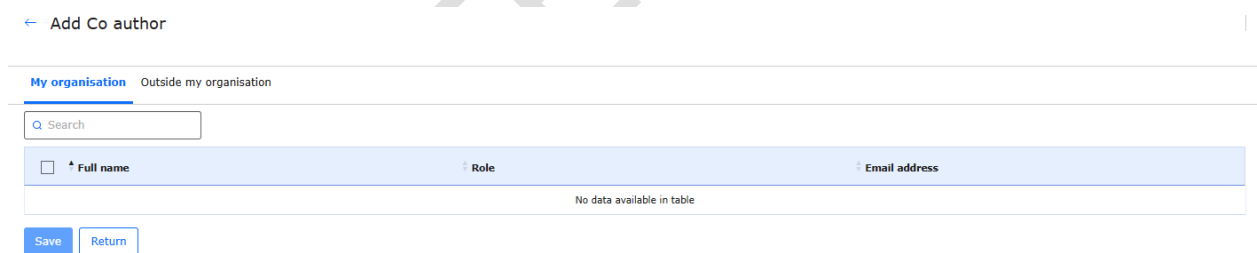
Coordinator(s) with implicit access to this application

Name	Email address	Role	Status
No data available in table			

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.

Figure 8. My Organisation Affiliate(s)' Tab



← Add Co author

My organisation Outside my organisation

Search

Full name	Role	Email address
No data available in table		

Save Return

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

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

Please note that in one go you can add:

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

Click on the **Save** button

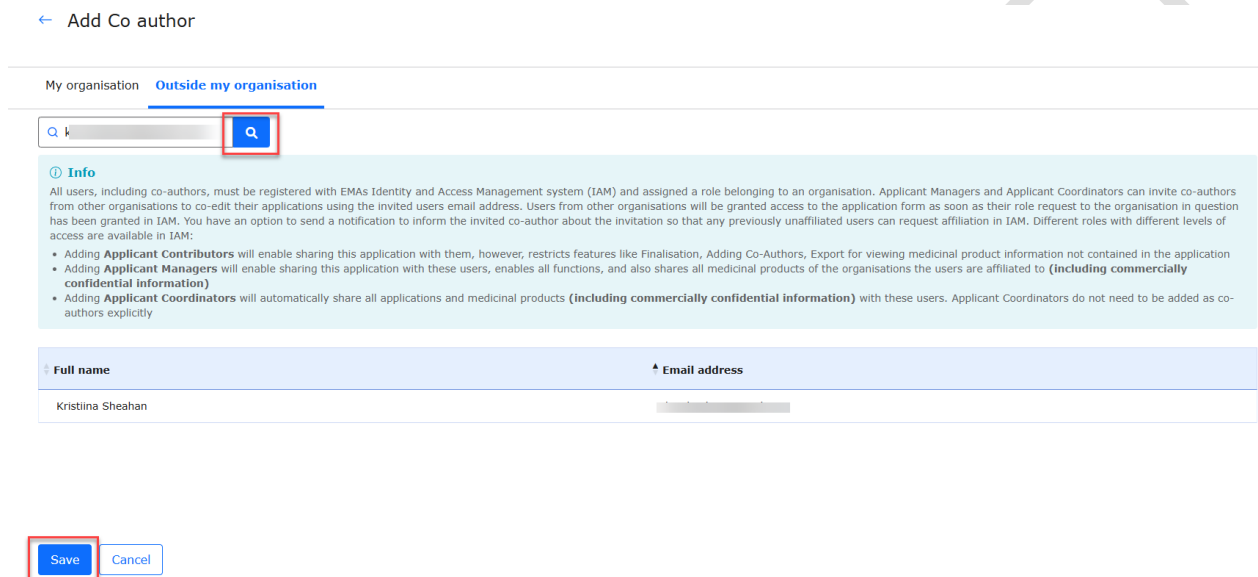
You will be prompted with a list of all added co-authors for that Application Form. It is to be noted that only users with the Role Status '**Affiliated**' can access / edit an Application Form.

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

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

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

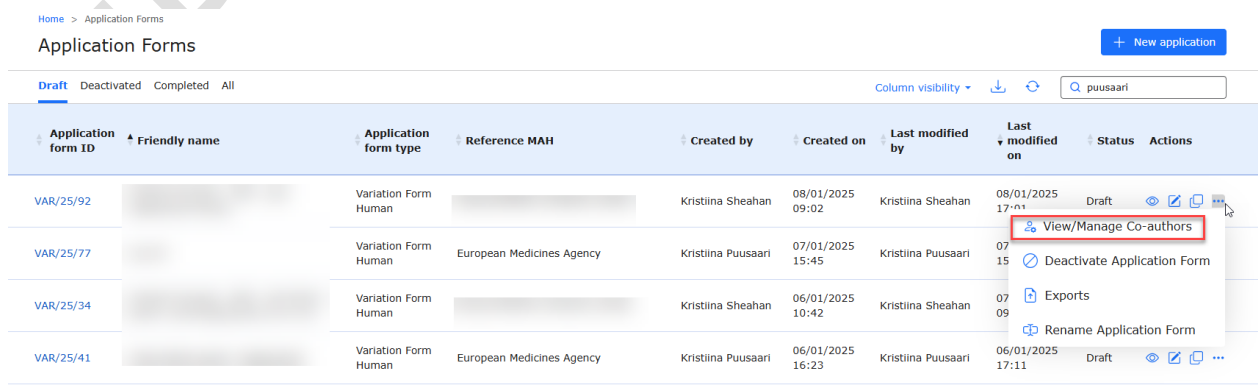
Figure 9. Add Co-author



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

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

Figure 10. View/Manage Co-authors



Application Form ID	Friendly name	Application form type	Reference MAH	Created by	Created on	Last modified by	Last modified on	Status	Actions
VAR/25/92		Variation Form Human		Kristiina Sheahan	08/01/2025 09:02	Kristiina Sheahan	08/01/2025 17:01	Draft	View/Manage Co-authors, Deactivate Application Form, Exports, Rename Application Form
VAR/25/77		Variation Form Human	European Medicines Agency	Kristiina Puusaari	07/01/2025 15:45	Kristiina Puusaari	07/15		Deactivate Application Form
VAR/25/34		Variation Form Human		Kristiina Sheahan	06/01/2025 10:42	Kristiina Sheahan	07/09		Exports
VAR/25/41		Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/01/2025 16:23	Kristiina Puusaari	06/01/2025 17:11	Draft	View/Manage Co-authors, Deactivate Application Form, Exports, Rename Application Form

Figure 11. Add Co-author



[Add Co-authors](#)

Name	Email address	Role ↑	Status
Kristina Sheahan		Applicant Manager	Affiliated

Coordinator(s) with implicit access to this application

Name	Email address	Role	Status
		Applicant Coordinator	Affiliated
		Applicant Coordinator	Affiliated
		Applicant Coordinator	Affiliated
		Applicant Coordinator	Affiliated

Close

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

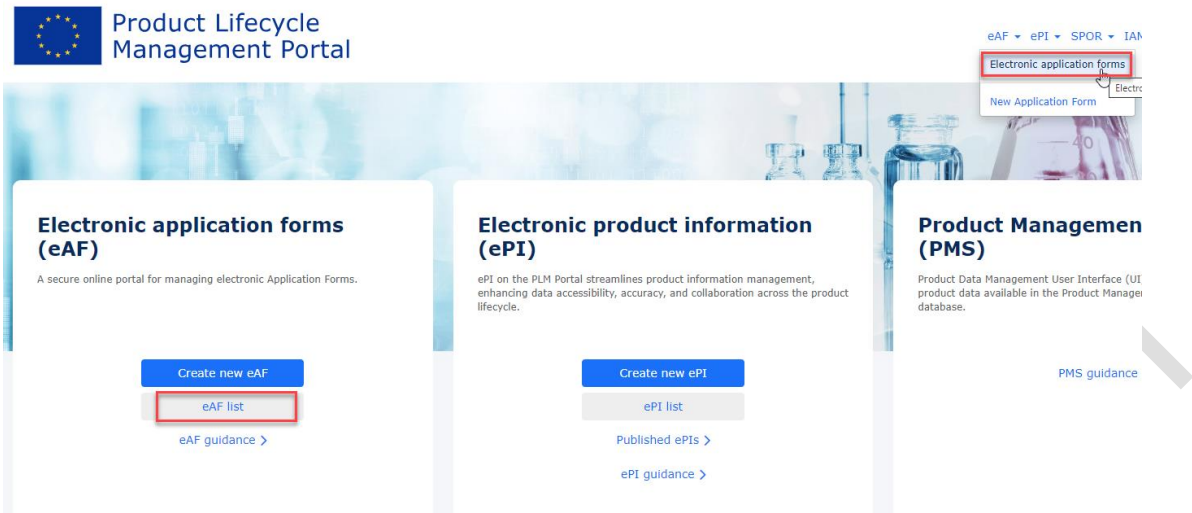
Industry users with an active EMA account and with the eAF **Applicant Manager** role can edit existing Application Forms which have been created by them;

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

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

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

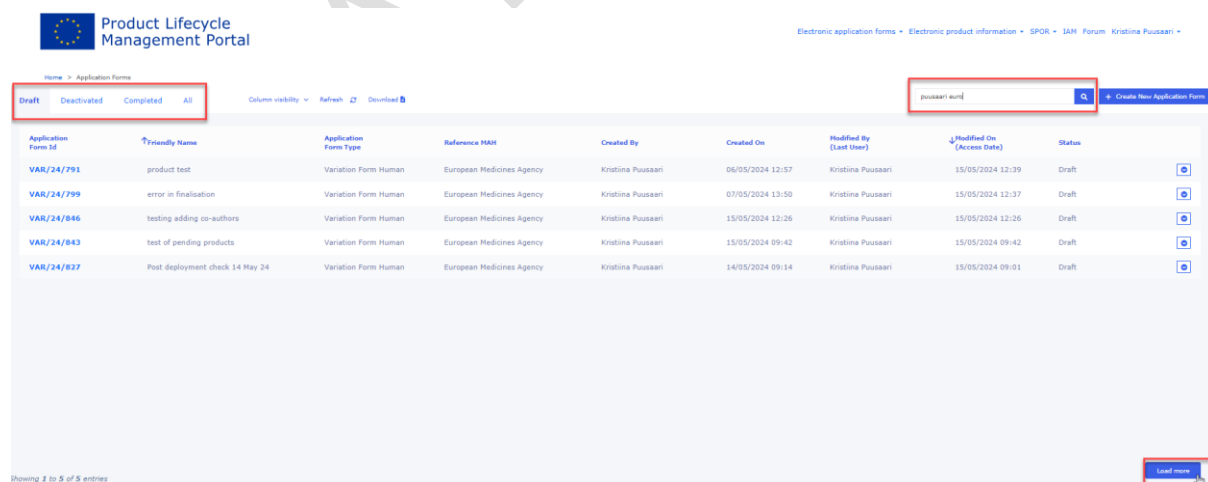
Figure 12. Application Forms



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

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

Figure 13. List of Application Forms



Home > Application Forms

Application Forms

[Draft](#) [Deactivated](#) [Completed](#) [All](#)

Column visibility

Application form ID	Friendly name	Application form type	Reference MAH	Created by	Created on	Last modified by	Last modified on	Status	Actions
VAR/25/1871	Kristina Puusaari - EMA - post deployment check create new application/co-author	Variation Form Human		Kristina Sheahan	17/03/2025 20:53	Kristina Sheahan	24/03/2025 14:18	Draft	
VAR/25/2050	SuperPill 50mg manufacturer update	Variation Form Human		Kristina Puusaari	24/03/2025 14:08	Kristina Puusaari	24/03/2025 14:08	Draft	
VAR/23/496	test	Variation Form Human		Kristina Puusaari	23/03/2023 11:45	Kristina Puusaari	19/03/2020 04:32		
VAR/23/431	System demo prep	Variation Form Human	European Medicines Agency	Kristina Puusaari	16/03/2023 13:45	Kristina Puusaari	19/03/2020 04:31		
VAR/23/370	retest additional info	Variation Form Human	European Medicines Agency	Kristina Puusaari	07/03/2023 09:16	Kristina Puusaari	19/03/2020 04:31		

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

In all four tabs, you may use:

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

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

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

As the options differ for application forms in the different tabs, click the 'three dots' button



, at the right hand-side of each row on the list of Application Form(s), to check which actions you can perform on that Application Form. Those actions also depend on your assigned access role(s)/permissions.

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



Table 1. Application Form operations

User Role name	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"> - View Application Form - Edit Application Form - View/Manage Co-authors 	<ul style="list-style-type: none"> - View Application Form - Edit Application Form - Exports - Deactivate Application Form - Clone Application Form - View/Manage Co-authors - Rename Application Form 		
Deactivated	<ul style="list-style-type: none"> - View Application Form - View Co-authors 	<ul style="list-style-type: none"> - View Application Form - View Co-authors - Exports - Clone Application Form - Reopen Application Form - Delete Application Form* 		
Completed	<ul style="list-style-type: none"> - View Application Form - View Co-authors 	<ul style="list-style-type: none"> - View Application Form - View Co-authors - Exports - Reopen Application Form - Clone Application Form - Deactivate Application Form 		
All	Operations depend on the Status of the Application Form. Refer to the above operations and statuses			
*	Feature not currently working			

Description of the different operations:

- Exports – export generates a PDF eAF document which contains an FHIR XML attachment,
- View Co-authors (available in the 'Deactivated and Completed tabs) – provides a (read-only) list of all previously added co-authors onto a given Application Form;

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

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

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

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

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

Home > Application Forms

Application Forms + New application

Draft Deactivated Completed All Column visibility [icon] [icon] [icon] Search

Application form ID	Friendly name	Application form type	Reference MAH	Created by	Created on	Last modified by	Last modified on	Status	Actions
VAR/24/2385		Variation Form Human			04/10/2024 12:08		09/01/2025 11:08	Completed	<input checked="" type="checkbox"/> Reopen Application Form <input checked="" type="checkbox"/> Deactivate Application Form Exports
VAR/25/116		Variation Form Human			08/01/2025 17:31		08/01/2025 17:54		
VAR/24/4105		Variation Form Human			10/12/2024 14:51		08/01/2025 16:37		
VAR/25/107		Variation Form Human			08/01/2025 13:29		08/01/2025 14:23	Completed	

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

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

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

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

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

Home > Application Forms

Application Forms + New application

Draft Deactivated Completed All Column visibility [icon] [icon] [icon] puusaari

Application form ID	Friendly name	Application form type	Reference MAH	Created by	Created on	Last modified by	Last modified on	Status	Actions
VAR/25/77	test KP	Variation Form Human	European Medicines Agency	Kristiina Puusaari	07/01/2025 15:45	Kristiina Puusaari	07/01/2025 15:56	Draft	[icon] [icon] [icon] [icon]
VAR/25/41	check before sprint 1 deployment	Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/01/2025 16:23	Kristiina Puusaari	06/01/2025 17:11	Draft	[icon] [icon] [icon] [icon] [icon] [icon]
		Variation Form			12/01/2023		26/12/2024		

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

This feature caters to two different scenarios:

1. The first scenario addresses situations where an application has been previously submitted, however subsequent requests for information or alterations have arisen. Users may want to retain the original, finalised version while making modifications for resubmission or to address queries. This functionality serves as **a solution for versioning**. It enables the creation of a clone of the original application, allowing modifications to be made, thus maintaining two distinct versions of the same application.
2. The second scenario pertains to **reuse of the application form particulars** and is comparable to **'save as'** which is very useful if you for example have another variation

application containing all or some of the same products as in previous application. Occasionally, it might be necessary to change Marketing Authorisation Holder (MAH) and access limitations might prevent the cloning of products, ensuring adherence to security protocols, and consequently, only other relevant information will be cloned.

Home > Application Forms > Draft Application Form

Create new application


1 Select Application Details 2 Add Co-Author

Application form type

Variation Form Human

Friendly name *

SuperPill 50mg manufacturer update

Reference MAH * 

European Medicines Agency x Q

Organisation details

Organisation ID ORG-100013412

Customer Account Number 1234567890

LOC ID LOC-100020264

LOC ID modified on 14/01/2025 17:01


Address Domenico Scarlattilaan 6
Amsterdam 1083 HS
Netherlands

Create & Next Cancel

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


1 Select Application Details 2 Add Co-Author

Co-authors added to this application Add Co-author

Full Name	Contact Email	Role ↑	Role Status
Noel Diamant	noel.diamant@pages.at	EMA Admin Assistant	Affiliated 

Coordinator(s) with implicit access to this application

Full Name	Contact E-Mail	Role	Role Status
Sindhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated

Previous
Next
Close


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



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

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

Just a moment

Please wait...

We are currently cloning application data. To ensure data integrity and prevent any loss, all operations are temporarily blocked. This process may take some time. Thank you for your patience and understanding.

[Return](#) [Refresh](#)

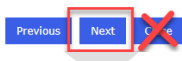
1 Select Application Details ✓ 2 Add Co-Author

Co-authors added to this application [Add Co-author](#)

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

Coordinator(s) with implicit access to this application

Full Name	Contact E-Mail	Role	Role Status
		Applicant Coordinator	Affiliated
	.ema.europa.eu	Applicant Coordinator	Affiliated





1 Select Application Details ✓ 2 Add Co-Author

Co-authors added to this application Add Co-author

Full Name	Contact Email	Role ↑	Role Status
Noel Diamant	noel.diamant@ages.at	EMA Admin Assistant	Affiliated

Coordinator(s) with implicit access to this application

Full Name	Contact E-Mail	Role	Role Status
Sindhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated

Previous Next Close

The selected scope is cloned

Product Lifecycle Management Portal

Home Products Management Service ePL Application Forms Forum SPOR LAM Noel Diamant

Pending Type(s) of Change(s) Variation Form Human / Version: 1.110 / Application for variation to a marketing authorisation Demo test ND / VAW/23/9/2 Last Saved: 06/11/2023 14:22

Product Selection Pending

Type(s) of Change(s) Pending

Procedural Information Pending

Proposed Changes Pending

Finalisation Pending

Variations included for this application

Refresh Search Add Scope

Scope	Selected	Description
A.5.b The activities for which the manufacturer/importer is responsible do not include batch release	1	A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release

Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
A.5.b - Variation Type IB - 1	Variation Type IB			

1 entries
Showing 1 to 1 of 1 entries

Save Validate Cancel Export



Procedural information will also all be cloned

Product Lifecycle Management Portal

Home | Products Management Service | ePL | Application Forms | Forum | SPOR | IAM | Noel Diamant

Pending | Procedural Information | Variation Form Human / Version: 1.110 / Application for variation to a marketing authorisation | Demo test ND / VAR/23/9/2 | Last Saved : 06/11/2023 14:22

Please add at least one Contact Person.

Procedural Information

Name and Address of MA Holder (Applicant)

Contact Person

Save | Validate | Cancel | Export

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

Product Lifecycle Management Portal

Home | Products Management Service | ePL | Application Forms | Forum | SPOR | IAM | Noel Diamant

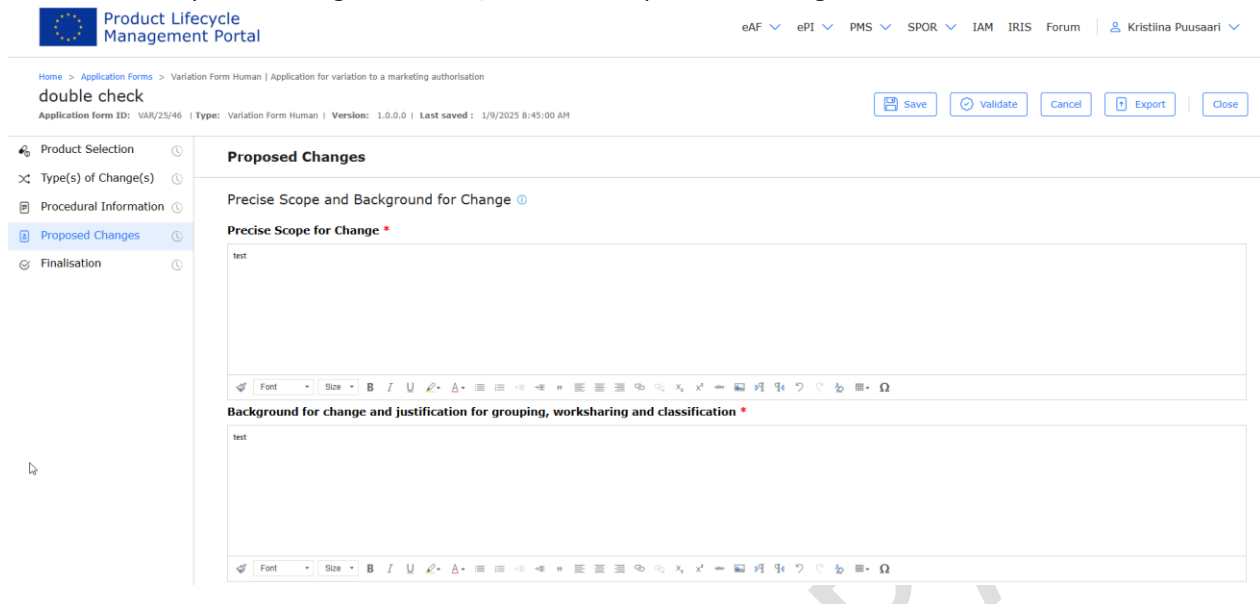
Pending | Procedural Information | Variation Form Human / Version: 1.110 / Application for variation to a marketing authorisation | Demo test ND / VAR/23/9/2 | Last Saved : 06/11/2023 14:22

Please add at least one Contact Person.

Procedural Information

Domain *	Human use	Type of Authorisation	Variation Procedure Number *
Type of Application	Single Regulatory Activity	Name †	Procedure Number †
Including a line extension	<input type="checkbox"/>	Decentralised Procedure	P1/N/1234/123
Worksharing ⓘ	<input type="checkbox"/>	National Procedure	
TD / Superproposing ⓘ	<input type="checkbox"/>	Change(s) concern(s) (for Type III and Type II variations only, tick all changes applicable)	Reference Number State *
Procedure Type ⓘ			Portugal
Name †		<input type="checkbox"/> Name	
Variation Type III			

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



Present and Proposed Changes

Add changes



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

2.1.5. Delete form function

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

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

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

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

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

2.1.7. Concurrent users

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

2.2. Product Selection

2.2.1. How to add a product in an Application Form

2.2.1.1. Unfiltered view (adding products without searching)

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

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

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

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

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

Figure 14. Add Product

Home > Electronic application forms list

Product selection update


Application form ID: VAR/25/403 | Type: Variation Form Human | Version: 1.0.0.0 | Last saved: 24 Mar 2025, 13:28

Save Validate Exports Refresh Close

- + Product selection ⌵
- × Types of changes ⌵
- ▣ Procedural info ⌵
- ▣ Proposed changes ⌵
- ☑ Finalisation ⌵

Product selection

Products concerned by this application ⓘ



Select product

No products have been selected in this application yet.

+ Select product

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

← Select products
Cancel Save

Application form ID: VAR/25/403 | Friendly name: Product select...

Column visibility

Show 10 rows ⌵

Clear filters

View selected products

	Full name	10 rows	Active substance	Authorisation country	MA holder	MA no.	MRP/CP no.	PMS ID
<input type="checkbox"/>	🔍 Search Full	<input checked="" type="checkbox"/>	Search Active subst	Search Authorisation cc	Search MA holder	Search MA no.	Search MRP/CP no.	Search PMS ID
No data available in table								


Showing 0 entries

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



Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.
Dantrium	Powder for solution for injection	Dantrolene sodium	Denmark	Norgine B.V.	10476	
<input checked="" type="checkbox"/> DANTRIUM 100 mg, gélule	Capsule, hard	Dantrolene sodium	France	Norgine B.V.		
<input type="checkbox"/> DANTRIUM 25-111g, gélule	Capsule, hard	Dantrolene sodium	France	Norgine B.V.	34009 321 560 0 9	

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

- If your access gives you option to select from many products, it is helpful to use the search and filtering options to By using the search and filter capabilities you can find the required medicinal product(s) more quickly. Also, if you have more than 500 medicinal products available you will **need** to use the filters to find the relevant product(s). You can use one or more column filters. It is also possible to sort the columns by clicking the column name.
- In the Select Product subpage, use available fields for defining the product search to select the applicable product(s). Different columns are available to allow users to select their preferred search criteria. It is possible to adjust the column visibility using the 'column visibility' option. Depending on the number of products available for each user the list may need to be filtered with multiple attributes. Please note that especially for products authorised through MRP/DCP or NP some attributes may be empty due to data issues or due to information not being available at that level, for example if the products are authorised on the packaged medicinal product level in the member state, there maybe not be a MA number available on the medicinal product level.
- Start the search by typing into any of the search fields and click '**enter**' to start the search or click the magnifying glass  to the left of the search filters.

Product Selection > View / Select Product

Column visibility Refresh Show 100 rows Clear Filters View Selected Products Filter

Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID
Abacavir/Lamivudine Viatris 600 mg/300 mg aprakotās tabletes	Film-coated tablet	Lamivudine, Abacavir	Latvia	Viatris Limited	17-0218	AT/H/0920/001	600001456380	
Abacavir/Lamivudine Viatris 600 mg/300 mg pievele dengtos tabletes	Film-coated tablet	Lamivudine, Abacavir	Lithuania	Viatris Limited		AT/H/0920/001	600001479647	
Abacavir/Lamivudine Viatris 600 mg/300 mg šūakase pāliemsenkatēģa tabletid	Film-coated tablet	Lamivudine, Abacavir	Estonia	Viatris Limited	974818	AT/H/0920/001	600001843282	
Abacavir/Lamivudinā Viatris 600 mg/300 mg comprimāte filmāte	Film-coated tablet	Abacavir, Lamivudine	Romania	Viatris Limited	10408/2017/05	AT/H/0920/001	600001608771	

Showing 1 to 4 of 4 entries

Save Cancel

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

Figure 15. List of Products

Column visibility Refresh Show 10 rows View Selected Products EMEA/H/C/002

Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
ABASAGLAR 100 units/mL KwikPen solution for injection in a pre-filled pen	Solution for injection	Insulin glargine	European Union	Eli Lilly Nederland B.V.	EU/1/14/944	EMEA/H/C/002835			
ABASAGLAR 100 units/mL Tempo Pen solution for injection in a pre-filled pen	Solution for injection	Insulin glargine	European Union	Eli Lilly Nederland B.V.	EU/1/14/944	EMEA/H/C/002835			

5. When you have found the products you wish to include in the form, please select the rows by clicking to them. It is not necessary to tick the tick box, selection can be done **clicking anywhere in the row**. Once you have selected the required products, click save at the bottom of the page.

Column visibility Refresh Show 10 rows View Selected Products Filter

Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID
ABILIFY 10 mg orodispersible tablets	Orodispersible tablet	Anipirazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	600000000449
ABILIFY 15 mg orodispersible tablets	Orodispersible tablet	Anipirazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	600000000450
ABILIFY 30 mg orodispersible tablets	Orodispersible tablet	Anipirazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	6000000004293

Showing 1 to 3 of 3 entries 1 rows selected

Save Cancel

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

6. Click on the **Save** button.

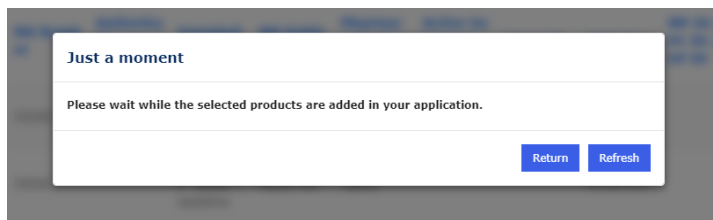
Column visibility ▾ Refresh ↻ Show 10 rows ▾ Clear Filters View Selected Products Filter

<input type="checkbox"/>	Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PHS ID
<input type="checkbox"/>	ability	orodisper	Search Active substance(s)	Search Authorization Country	Search MA Holder	Search MA Nr.	Search MRP/CP Nr.	Search PHS ID
<input type="checkbox"/>	ABILIFY 10 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60000000449
<input checked="" type="checkbox"/>	ABILIFY 15 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60000000450
<input type="checkbox"/>	ABILIFY 30 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	600000004293

Showing 1 to 3 of 3 entries

Processing... Cancel

Please note: After clicking on the “Save” button, the system will perform several adjustments and integration in the background while the product and related packages are added to the application form. While these ‘background maintenance’ activities are happening, editing the form is blocked by a the maintenance pop up window. Please note that the duration that further actions on the form are blocked by the pop up depends on the number of selected medicinal products and the number of available packages for those medicinal products. We are currently looking at ways to reduce the timing that it takes to perform these background activities:



- The message will remain on the screen until the background processes have finished. The “Return” button will redirect the user to the **application form list**, and the “Refresh” button will refresh the current page.
- Once the pop up disappears, you are presented with a list of your selected products. You can click the arrow on the left side of the Medicinal Product name to expand to view the list packaged medicinal products.

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

Products concerned by this application

Column visibility Show 10 rows Refresh Associate MRP No. Search + Add Product

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA No.	HRP / CP No.	PHS ID	MP ID	Authorisation Status	HSP Variation No.	Nr. of Selected Packages
<input type="checkbox"/> ABILIFY 15 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	600000000450		Valid - Transferred marketing authorisation		0/3

Selected Packaged Medicinal Product(s)

Full Name	Pack Size	Package Description	MA Number	Package ID	Authorisation Status
<input type="checkbox"/> ABILIFY 15 mg orodispersible tablets	28 x 1 tablets (unit dose)	Packaging: blister (alu/alu), Package size: 28 x 1 tablets (unit dose)	EU/1/04/276/028		Valid - Transferred marketing authorisation
<input type="checkbox"/> ABILIFY 15 mg orodispersible tablets	14 x 1 tablets (unit dose)	Packaging: blister (alu/alu), Package size: 14 x 1 tablets (unit dose)	EU/1/04/276/027		Valid - Transferred marketing authorisation
<input type="checkbox"/> ABILIFY 15 mg orodispersible tablets	49 x 1 tablets (unit dose)	Packaging: blister (alu/alu), Package size: 49 x 1 tablets (unit dose)	EU/1/04/276/029		Valid - Transferred marketing authorisation

Showing 1 to 3 of 3 entries

Showing 1 to 1 of 1 entries

9. If you wish to add more products, please repeat the steps above, however, please note that it is possible to select as many products as needed at one go. The product selection process works like a 'shopping basket' function where you select the product by ticking the box and you can clear filters and launch new searches until you have selected all products you need, and then click save.

For very large applications containing several hundreds of medicinal products, we are aware of intermittent issues. When adding large numbers of products in the form, it is recommended to do this in batches to avoid errors. Please note that the team is working hard on improving the performance and functioning of the forms in case of large and very large applications.

2.2.2. Viewing selected products

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

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

View selected products

Product Selection > View / Select Product

Search visibility Refresh Show 10 rows Clear Filters [View Selected Products](#) Filter

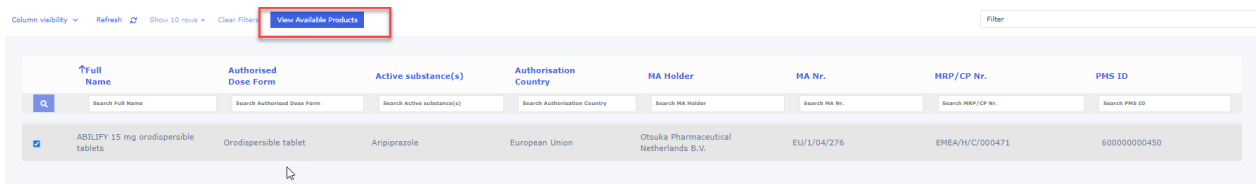
Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA No.	HRP / CP No.	PHS ID
<input type="text" value="Search Full Name"/>	<input type="text" value="Search Authorised Dose Form"/>	<input type="text" value="Search Active substance(s)"/>	<input type="text" value="Search Authorisation Country"/>	<input type="text" value="Search MA Holder"/>	<input type="text" value="Search MA No."/>	<input type="text" value="Search HRP/CP No."/>	<input type="text" value="Search PHS ID"/>

No data available in table

Showing 0 to 0 of 0 entries 0 rows selected

Save Cancel

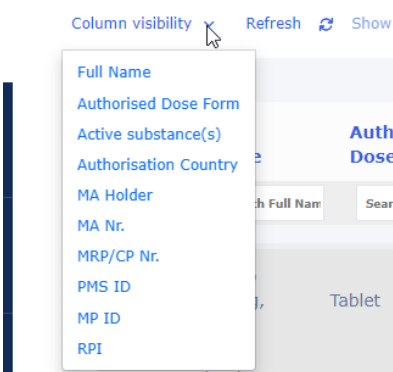
Figure 16. View Available Products



Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID
ABILIFY 15 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/N/C/000471	60000000450

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

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



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

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

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

Figure 17. Packaged Medicinal Product(s)

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.	PMS ID	Nr. of Selected Packages
ABILIFY 1 mg/ml oral solution	Oral solution	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EHEA/N/C/000471		0/3

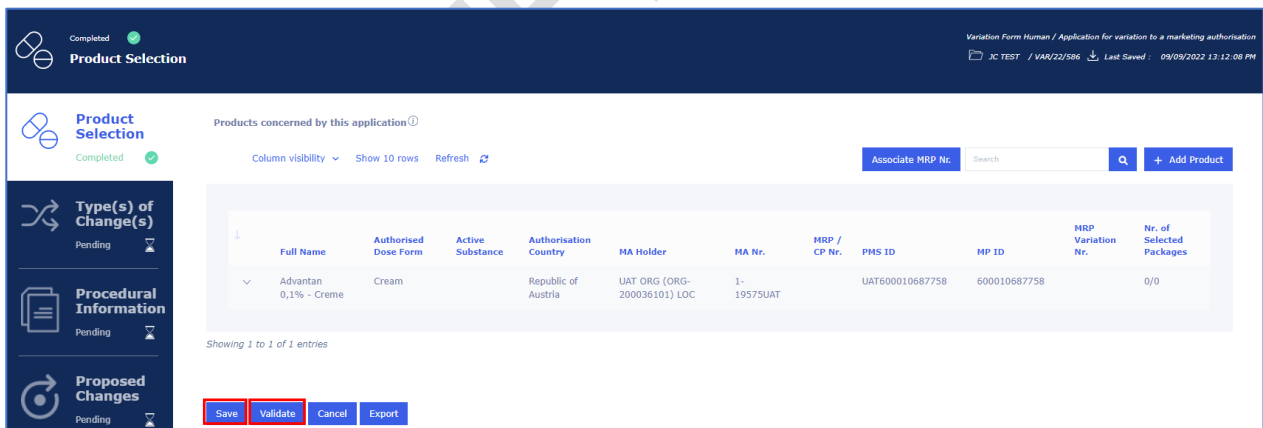
Selected Packaged Medicinal Product(s)

Full Name	Pack Size	Package Description	MA Number	Package ID	Authorisation Status
ABILIFY 1 mg/ml oral solution	1 bottle + 1 cup + 1 calibrated dropper	Packaging: bottle (PET), Package size: 1 bottle + 1 cup + 1 calibrated dropper, Content: 50 ml	EU/1/04/276/033		Valid - Transferred marketing authorisation
ABILIFY 1 mg/ml oral solution	1 bottle + 1 cup + 1 calibrated dropper	Packaging: bottle (PET), Package size: 1 bottle + 1 cup + 1 calibrated dropper, Content: 150 ml	EU/1/04/276/034		Valid - Transferred marketing authorisation
ABILIFY 1 mg/ml oral solution	1 bottle + 1 cup + 1 calibrated dropper	Packaging: bottle (PET), Package size: 1 bottle + 1 cup + 1 calibrated dropper, Content: 480 ml	EU/1/04/276/035		Valid - Transferred marketing authorisation

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

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

Figure 18. Save and Validate Buttons



Completed Product Selection

Variation Form Human / Application for variation to a marketing authorisation

JC TEST / VAR/22/586 Last Saved: 09/09/2022 13:12:08 PM

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.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG-200036101) LOC	1-19575UAT		UAT500010687758	600010687758		0/0

Showing 1 to 1 of 1 entries

Save **Validate** Cancel Export

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

DISCLAIMER: the **Associate MRP Nr.** feature applies to WS variations containing CAPs and non-CAPs and for variations containing non-CAPs only. For CAP or pure NP only variations this feature **cannot** be used.

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

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

Figure 19. Associate MRP Nr. Button

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	Authorisation Status	MSP Variation Nr.	Nr. of Selected Packages
✓ ENGERIX B 10 micrograms/0.5 ml Suspension for injection in pre-filled syringe Hepatitis B (rDNA) vaccine (adsorbed) (HBV)	Suspension for injection in pre-filled syringe	HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Malta	Glaxosmithkline (Ireland) Limited	MA192/02101		600001438133		Valid		0/1
✓ ENGERIX B 20 micrograms/1 ml Suspension for injection in pre-filled syringe Hepatitis B (rDNA) vaccine (adsorbed) (HBV)	Suspension for injection in pre-filled syringe	HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Malta	Glaxosmithkline (Ireland) Limited	MA192/02102		600001604005		Valid		0/1
✓ ENGERIX-B 20 mikrogram/1 ml Injeksjonsvæske, suspensjon.Vaksine mot hepatitt B (rDNA) (adsorbent) (HBV)	Suspension for injection	HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Norway	Glaxosmithkline AS	7548	BE/H/0009/001	600001632366		Valid		0/1
✓ ENGERIX-B 10 mikrogram/0,5 ml Injeksjonsvæske, suspensjon i ferdigfylt sprayte Vaksine mot hepatitt B (rDNA) (adsorbent) (HB)	Suspension for injection in pre-filled syringe	HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Norway	Glaxosmithkline AS	01-4702	BE/H/0009/002	600001695983		Valid		0/1

3. You will see a list of MRP/DCP products you selected in a previous step. You can then add the MRP Variation number for the relevant products in the field called MRP Variation Number and select, by clicking the row, the relevant product(s). Once you have finished selecting the product(s), press the **Update** button. Repeat the step to add the relevant MRP variation number to each respective product.

Column visibility ▾ Refresh ↻

search 🔍

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP / CP Nr.	PHS ID	MP ID	MRP Variation Nr.
☐ ENGERIX-B	injection in pre-filled syringe	CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Norway	Glaxosmithkline AS	01-4702	BE/H/0009/002	600001695983		
☑ ENGERIX-B	Suspension for injection	HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Norway	Glaxosmithkline AS	7548	BE/H/0009/001	600001632366		

Showing 1 to 2 of 2 entries

MRP Variation Number *
 Update **Return**

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

Products concerned by this application^①

Column visibility Show 10 rows Refresh

Associate MRP No. Search + Add Product

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr. ^①	MRP / CP Nr.	PHS ID	HP ID	Authorisation Status	MRP Variation Nr.	Nr. of Selected Packages
ENGERIX-B 10 mikrogram/0,5 ml Injeksjonsvæske, suspensjon i ferdigfylt sprøyte Vaksine mot hepatitt B (rDNA) (adsorbent) (HB)	Suspension for injection in pre-filled syringe	HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Norway	Glaxosmithkline AS	01-4702	BE/H/0009/002	600001695983		Valid	BE/H/0009/002/WS000	0/1
ENGERIX-B 20 mikrogram/1 ml Injeksjonsvæske, suspensjon.Vaksine mot hepatitt B (rDNA) (adsorbent) (HBV)	Suspension for injection	HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED	Norway	Glaxosmithkline AS	7548	BE/H/0009/001	600001632366		Valid	BE/H/0009/001/WS000	0/1

Hepatitis B

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

2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

MRP Variation Number⁸ BE/H/0009/001/WS000

Active Substance

HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED

MA Number(s) ⁸	Full name ²¹	MA Holder name	Member state	Pharmaceutical Form ²²
7548	ENGERIX-B 20 mikrogram/1 ml Injeksjonsvæske, suspensjon.Vaksine mot hepatitt B (rDNA) (adsorbent)	Glaxosmithkline AS	Norway	Suspension for injection

MRP Variation Number⁸ BE/H/0009/002/WS000

Active Substance

HEPATITIS B VIRUS SURFACE ANTIGEN [PRODUCED IN S. CEREVISIAE CELLS BY RDNA] ADSORBED ON ALUMINUM HYDROXIDE, HYDRATED

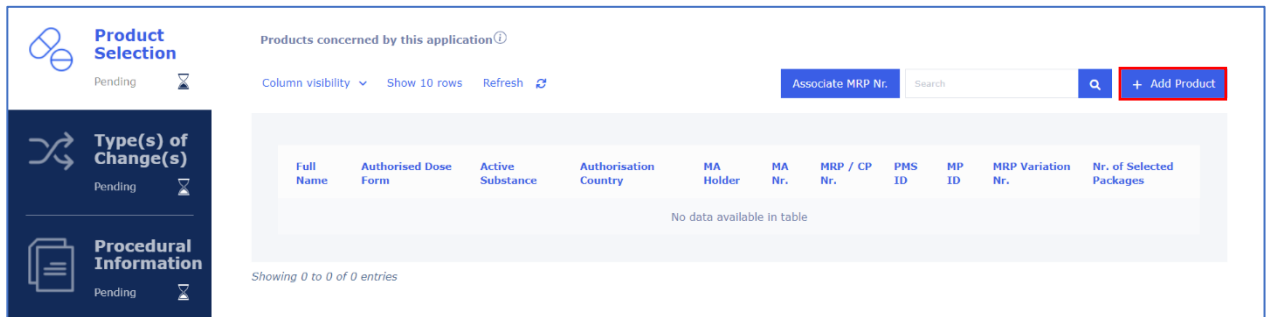
MA Number(s) ⁸	Full name ²¹	MA Holder name	Member state	Pharmaceutical Form ²²
01-4702	ENGERIX-B 10 mikrogram/0,5 ml Injeksjonsvæske, suspensjon i ferdigfylt sprøyte Vaksine mot hepati	Glaxosmithkline AS	Norway	Suspension for injection in pre-filled syringe

2.2.4. How to delete a product from an Application Form

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

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

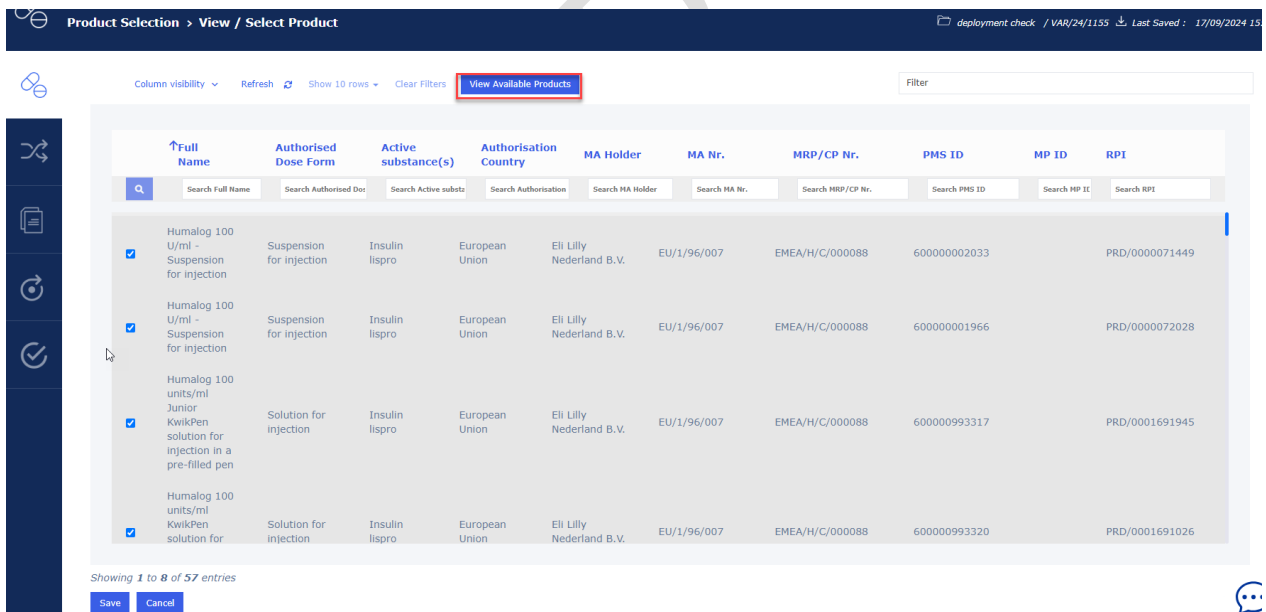
Figure 20. Add Product



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

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

Figure 21. View Available Products



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

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

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

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

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

Known limitations:

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

- The search should be triggered with press of 'enter' however, it is not always responsive and you may need to click the magnifying glass on the left side of the search grid
- There are number of various data quality issues in the system, for some we are currently working on technical solutions, some are due to the data quality from xVMPD. Here, some examples of known data issues;
 - Products authorised in **Finland** are submitted to xEVMPD with both, the Finnish name and the Swedish language name. The system currently 'randomly' picks one of these entries and product names for products authorised in Finland will appear, either in Finnish or Swedish language. We are currently working on a solution for this issue and once the fix is in place, only the Finnish language entry will be available for selection.
 - Products authorised in **Belgium** have similar issue, however, they appear randomly with either Flemish, French or German language name. We are still looking for solution to ensure that the products can be searched with the 'correct' name.
 - **Nullified** products (affecting CAPs and non-CAPs) – small number of nullified products (i.e. products that are not available for selection are still listed and visible in the eAF, however, upon selection they cause an error in the form. Unfortunately we are not able to provide a list of such nullified products at this time as they change. We are currently implementing a filter in the eAF so that these products will no longer be visible and available for selection in the eAF.
 - **Duplicate** products (affecting CAPs and non-CAPs): due to data errors coming from xEVMPD/PMS some packaged medicinal products are currently visible under 2 different medicinal products. This will cause an error in the eAF and user will not be able to continue the use of the web based eAF until this data error is corrected. If you are preparing an eAF and experience this issue, please **raise service desk ticket** using the [EMA service now](#)

- When you have filtered the list with number of search criteria and you adjust column visibility, the search attributes are cleared.

2.3. Type(s) of change(s)

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

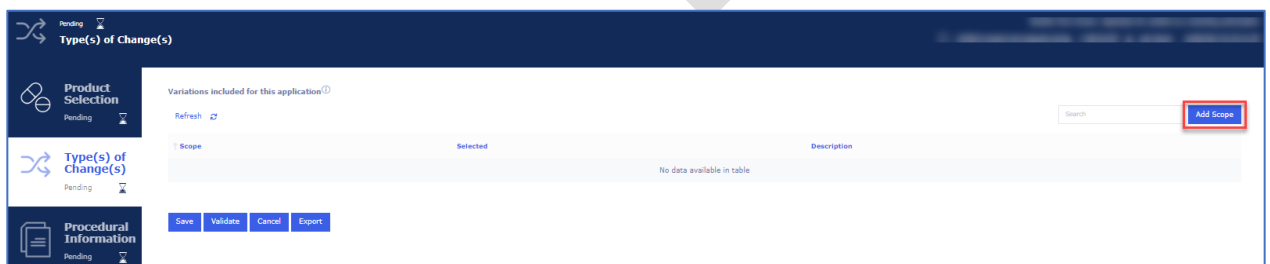
Industry users with the eAF Applicant Manager role or the eAF Applicant Coordinator role and NCA users with the eAF Competent Authority User role may add/delete scopes in an Application Form.

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

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

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

Figure 22. Add Scope




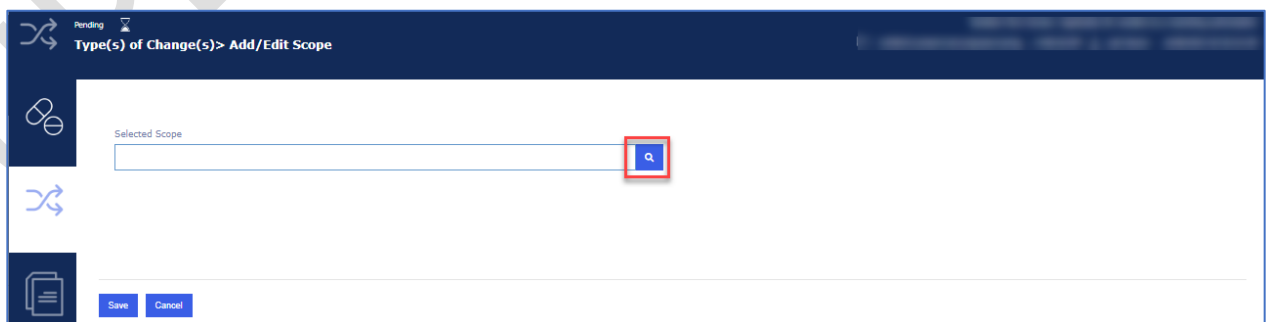
3. In the Add/Edit Scope subpage, launch the search for scope (variation classification category) selection by clicking on the magnifying glass . The scopes (categories) cannot be searched in Add/Edit scope subpage. Clicking the magnifying glass will open the 'Select scope window' where you can select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

Figure 23. Select Scope



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

the correct scope (the list is not auto filtered, you will need to **click enter** or the magnifying glass to filter further). Please **note** that the search is **not** case sensitive, i.e. you do not need to use capital letters. Please note use of **roman** numbers where relevant (for example to search for C.I.6, you will need to type c.i.6, not c.1.6). If you wish to search using the 'text' part of the scope, please note that you need to add an 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.

Figure 24. Example of Search using Classification Code

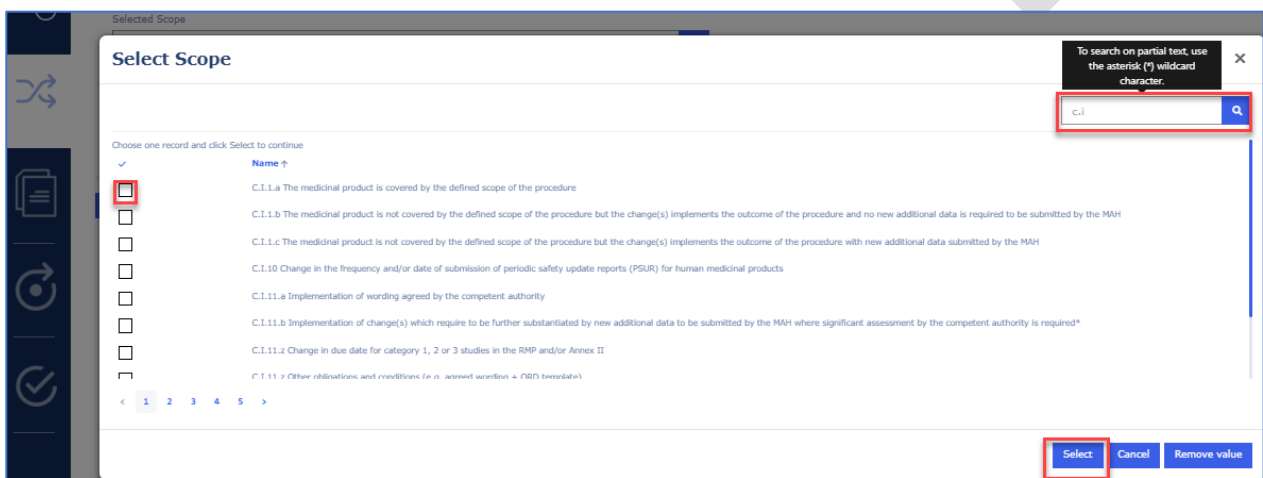
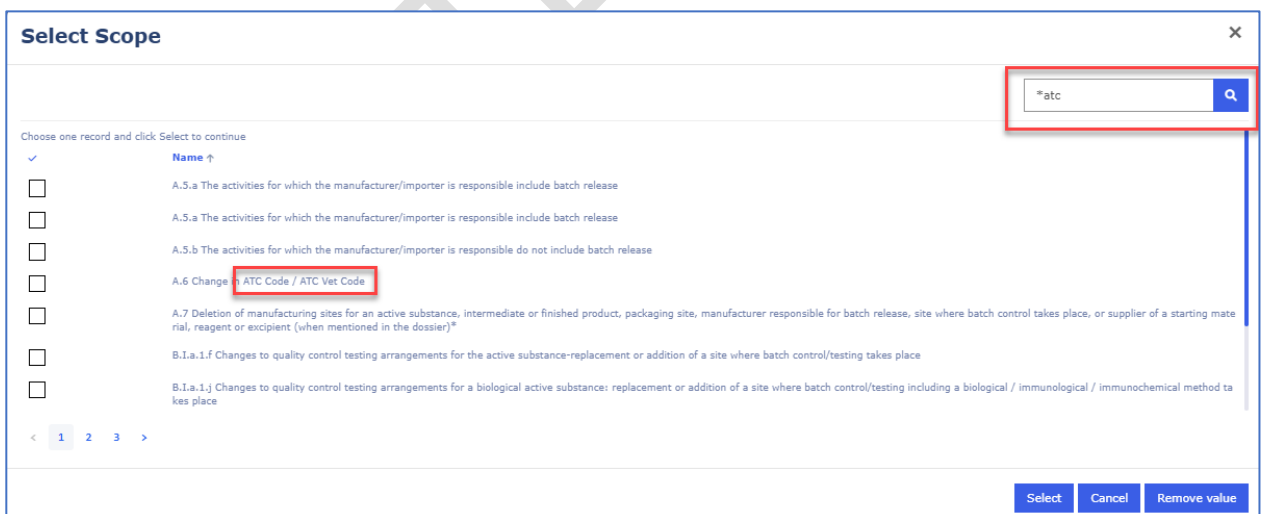


Figure 25. Example of Search using Wild Card and Text



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


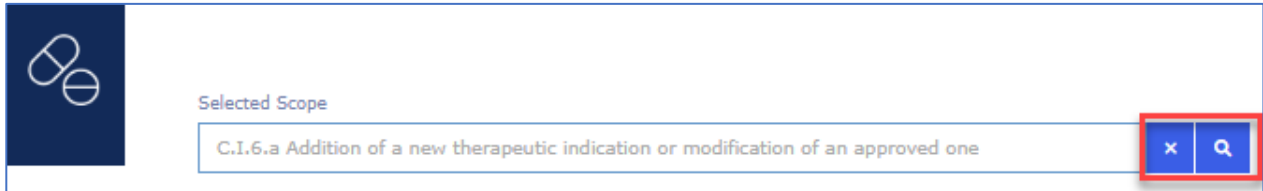
Upon clicking the **Select** button you will be taken back to the 'Add/Edit Scope' page where the first line will now display the selected scope. Clicking the 'X' will remove the scope and you can then click on the magnifying glass  again to return to the scope selection window.

Figure 26. Cancel and Select Scope




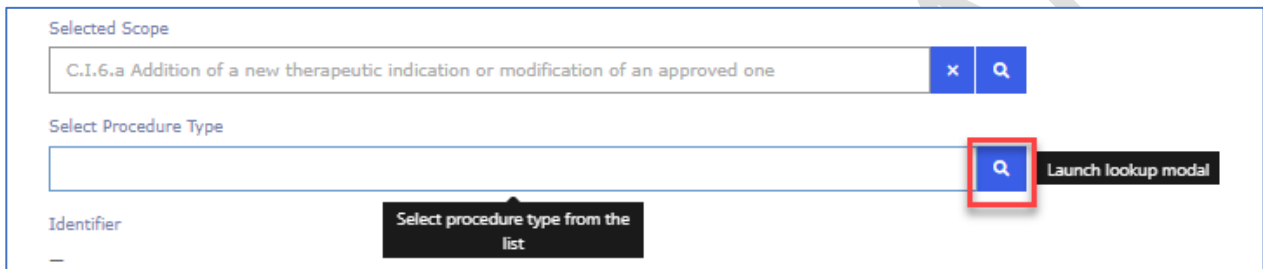
7. Click on the magnifying glass  to 'Select Procedure Type'

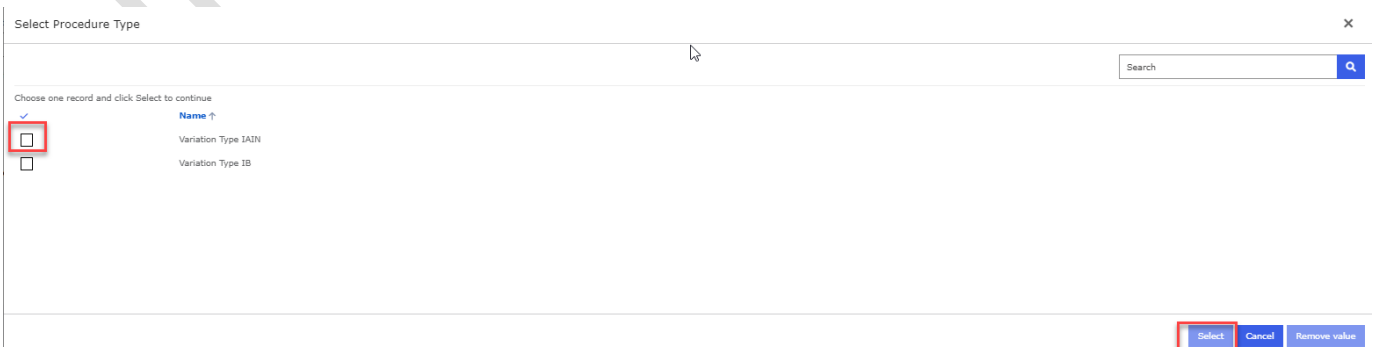
Figure 27. Select Procedure Type



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

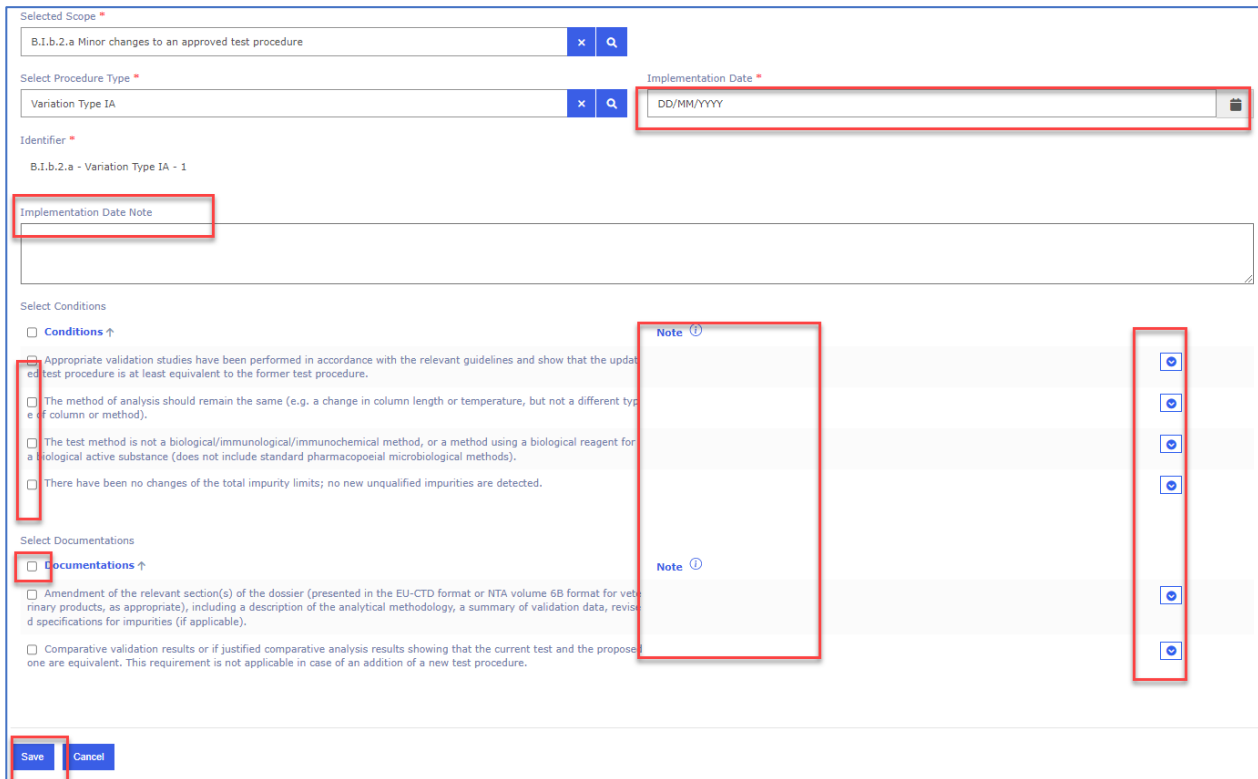
8. Click anywhere on the line to select the procedure type and then click the **Select** button to confirm the selection of the procedure type. If the procedure type you wish to select is not available, however, it appears in the classification guideline or should be available based on the business rules,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

Figure 28. Select Procedure Type



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

Figure 29. Option Selection



For Type IA/Type IA_{IN} you must add an Implementation date (either by selecting it from a calendar or by providing the date in format DD/MM/YYYY e.g.: 31/12/2022). 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.

Known issues:

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

There is another known, intermitted issue affecting the number of the selected scopes on the summary page. This is simply an issue in the web UI, the correct number of scopes is reflected in the exported pdf.

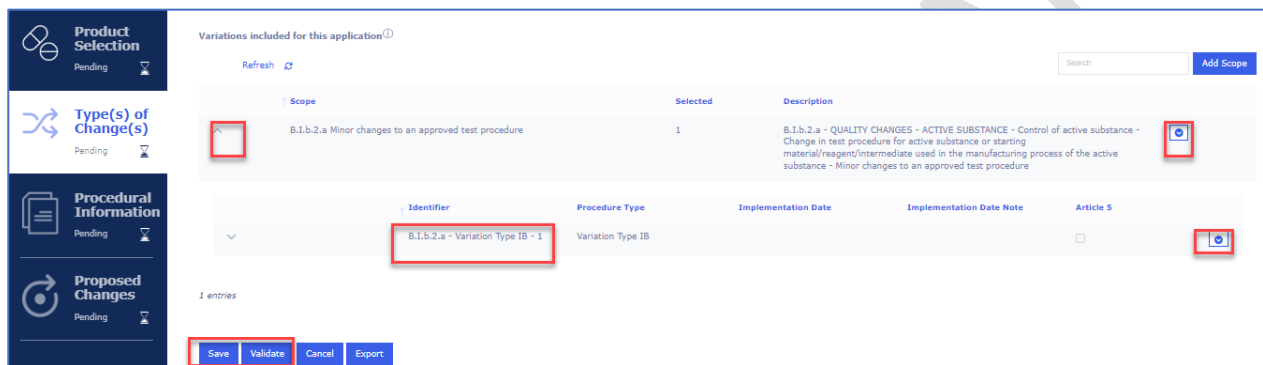
Due to intermitted nature of these issues, it is very hard to find the cause. We invite users to report these issues via servicedesk when encountered so that we can better understand the circumstances during which these issues occur.

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

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

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

Figure 30. Summary of Selection



Scope	Selected	Description
B.I.b.2.a Minor changes to an approved test procedure	1	B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure


Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
B.I.b.2.a - Variation Type IB - 1	Variation Type IB			<input type="checkbox"/>



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.





- If you need to add the same scope more than one, please use the '**Clone scope**' button. This will allow fast and easy way to include the same scope in the form multiple times. If you do not wish to use the clone feature, it is also possible to add the same scope multiple times or to select a different scope, please repeat the step by clicking 'Add scope' button. You can do this as many times as needed.
- Please note that if the same scope is added multiple times, either manually or using clone scope function, these are differentiated by using a sequential number for each scope. This will help you to identify the scopes when you are linking the scopes and the packaged medicinal products in Present and Proposed section.

Figure 31. Add Scope

Variations included for this application[⌵]

Refresh 

Scope	Selected	Description
 C.I.6.a Addition of a new therapeutic indication or modification of an approved one	<input checked="" type="checkbox"/>	C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one 

Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
 C.I.6.a - Variation Type II - 1	Variation Type II			<input type="checkbox"/> 
 C.I.6.a - Variation Type II - 2	Variation Type II			<input type="checkbox"/> 

2 entries

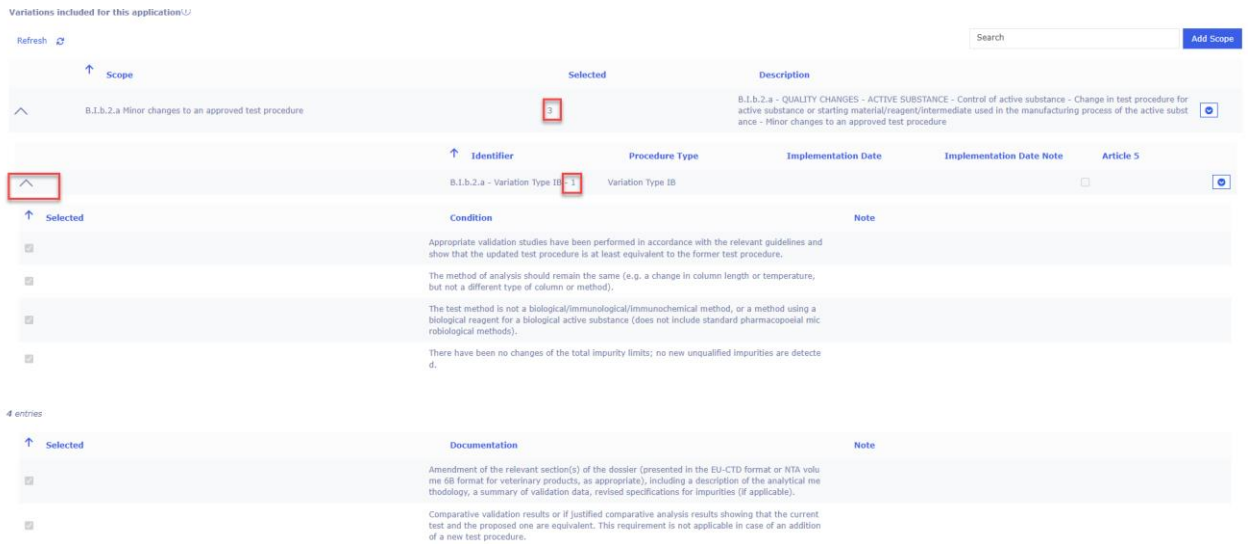
Showing 1 to 1 of 1 entries

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

2.3.2. Clone scope

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

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



Variations included for this application

Refresh

Search Add Scope

Scope	Selected	Description
B.I.b.2.a Minor changes to an approved test procedure	3	B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure

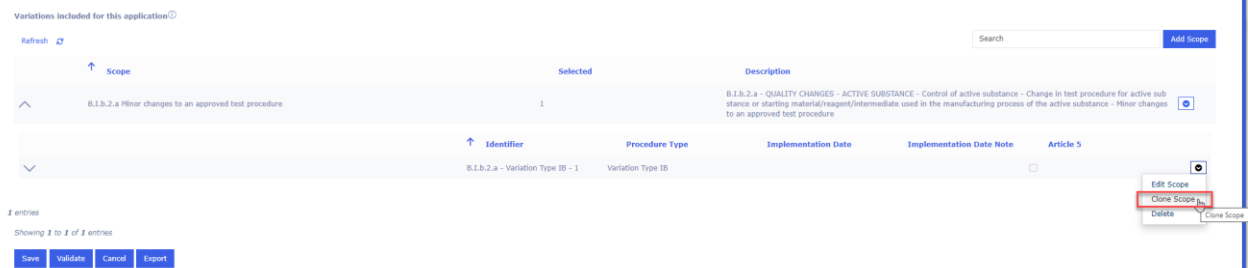
Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
B.I.b.2.a - Variation Type IB - 1	Variation Type IB			

4 entries

Selected	Condition	Note
<input checked="" type="checkbox"/>	Appropriate validation studies have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure.	
<input checked="" type="checkbox"/>	The method of analysis should remain the same (e.g. a change in column length or temperature, but not a different type of column or method).	
<input checked="" type="checkbox"/>	The test method is not a biological/immunological/immunochemical method, or a method using a biological reagent for a biological active substance (does not include standard pharmacopoeial microbiological methods).	
<input checked="" type="checkbox"/>	There have been no changes of the total impurity limits; no new unqualified impurities are detected.	

Selected	Documentation	Note
<input checked="" type="checkbox"/>	Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate), including a description of the analytical methodology, a summary of validation data, revised specifications for impurities (if applicable).	
<input checked="" type="checkbox"/>	Comparative validation results or if justified comparative analysis results showing that the current test and the proposed one are equivalent. This requirement is not applicable in case of an addition of a new test procedure.	

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



Variations included for this application

Refresh

Search Add Scope

Scope	Selected	Description
B.I.b.2.a Minor changes to an approved test procedure	1	B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure

Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
B.I.b.2.a - Variation Type IB - 1	Variation Type IB			

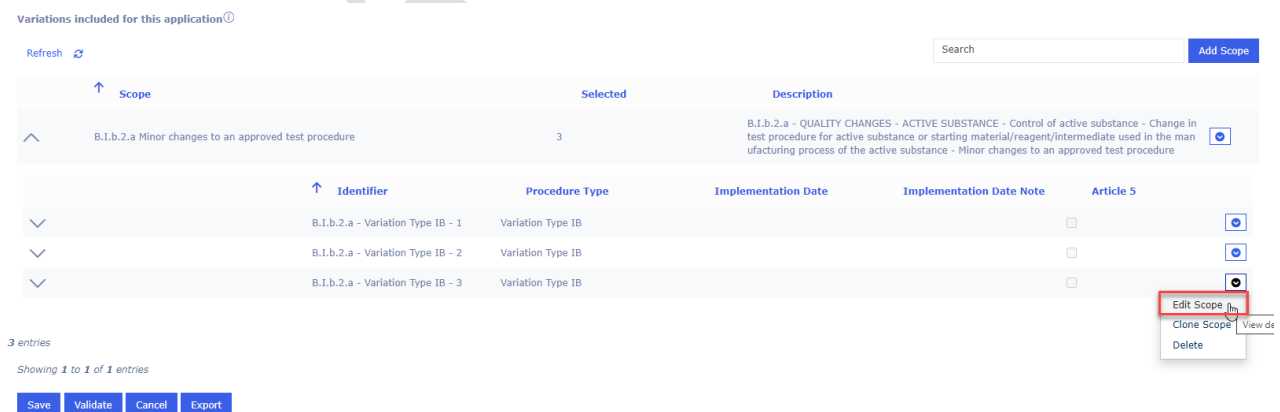
1 entries

Showing 1 to 1 of 1 entries

Save Validate Cancel Export

Edit Scope
Clone Scope
Delete

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



Variations included for this application

Refresh

Search Add Scope

Scope	Selected	Description
B.I.b.2.a Minor changes to an approved test procedure	3	B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure

Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
B.I.b.2.a - Variation Type IB - 1	Variation Type IB			
B.I.b.2.a - Variation Type IB - 2	Variation Type IB			
B.I.b.2.a - Variation Type IB - 3	Variation Type IB			

3 entries

Showing 1 to 1 of 1 entries

Save Validate Cancel Export

Edit Scope
Clone Scope
Delete

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

Variations included for this application

Refresh

Search Add Scope

Scope	Selected	Description
B.1.b.2.a Minor changes to an approved test procedure	3	B.1.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure

Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5
B.1.b.2.a - Variation Type IB - 1	Variation Type IB			
B.1.b.2.a - Variation Type IB - 2	Variation Type IB			
B.1.b.2.a - Variation Type IB - 3	Variation Type IB			

3 entries
Showing 1 to 1 of 1 entries

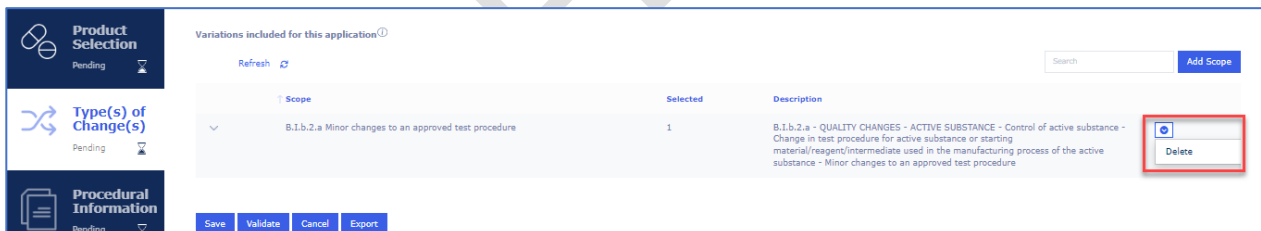
Save Validate Cancel Export

2.3.3. How to delete a scope in an application

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

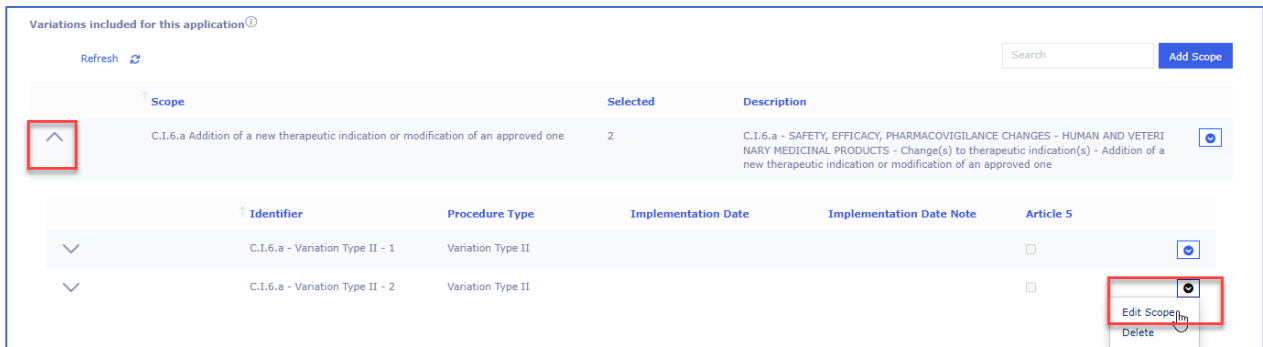
1. Access an existing or create a new Application Form. See sections, 2.1.2 and 2.1.3 for further details
2. In the Type(s) of Change(s) page, click the small arrow at the end of the scope you wish to delete and select 'Delete'.

Figure 32. Delete Scope



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

Figure 33. Edit Scope

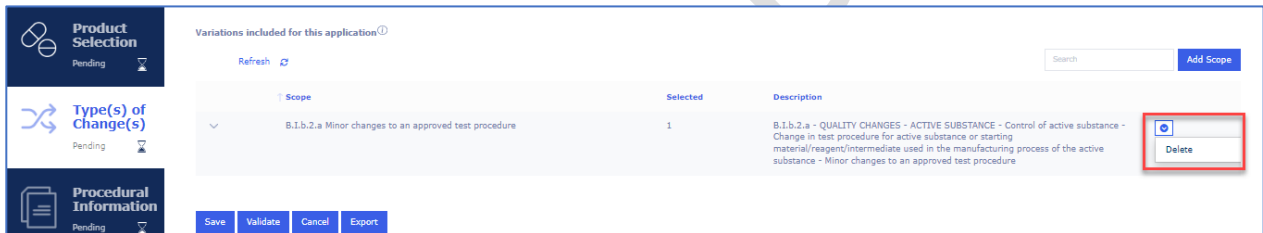


2.3.4. How to delete a scope in an application

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

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

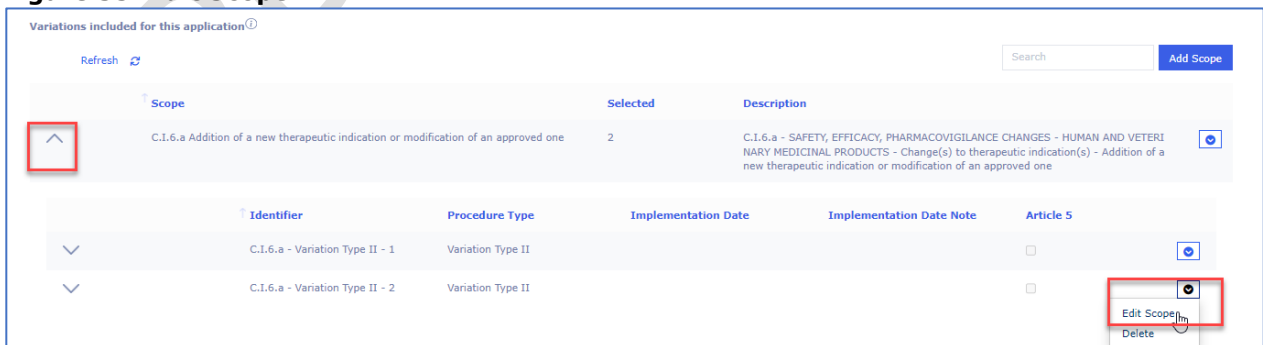
Figure 34. Delete Scope



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

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

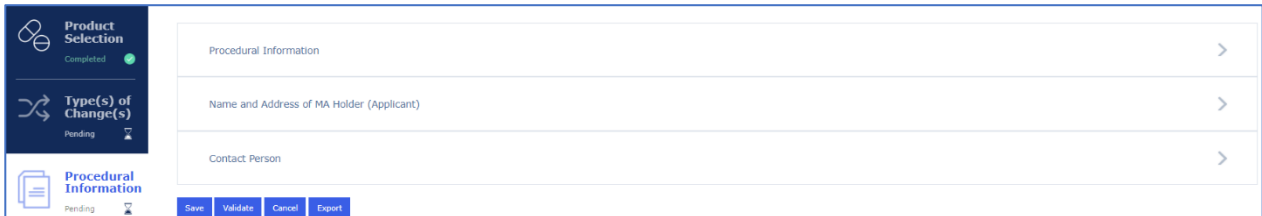
Figure 35. Edit Scope



2.4. Procedural Information

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

Figure 36. Procedural Information Section Overview



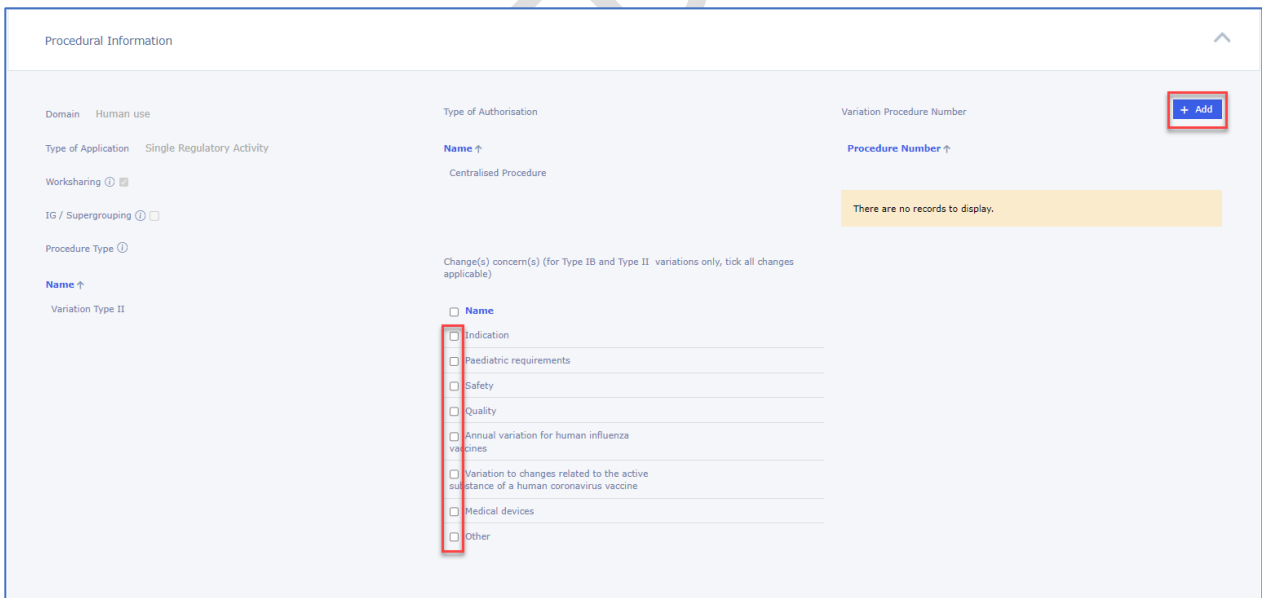
2.4.1. Procedural Information

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

It is not possible to manually edit these selections.

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

Figure 37. Sub-section: Procedural Information



- *Domain: This is always 'Human Use' as the variation form currently only contains human medicinal products.*
- *Worksharing; this field is auto calculated and is ticked by the system when more than one 'Centrally Authorised Products' (CAPs) i.e. products with different EMEA/H/ number have been selected or when a mix of different CAPs and non-CAPs or a mix of different non-CAPs are selected. Please note that the product selection is on 'Medicinal Product' level i.e. if the product*

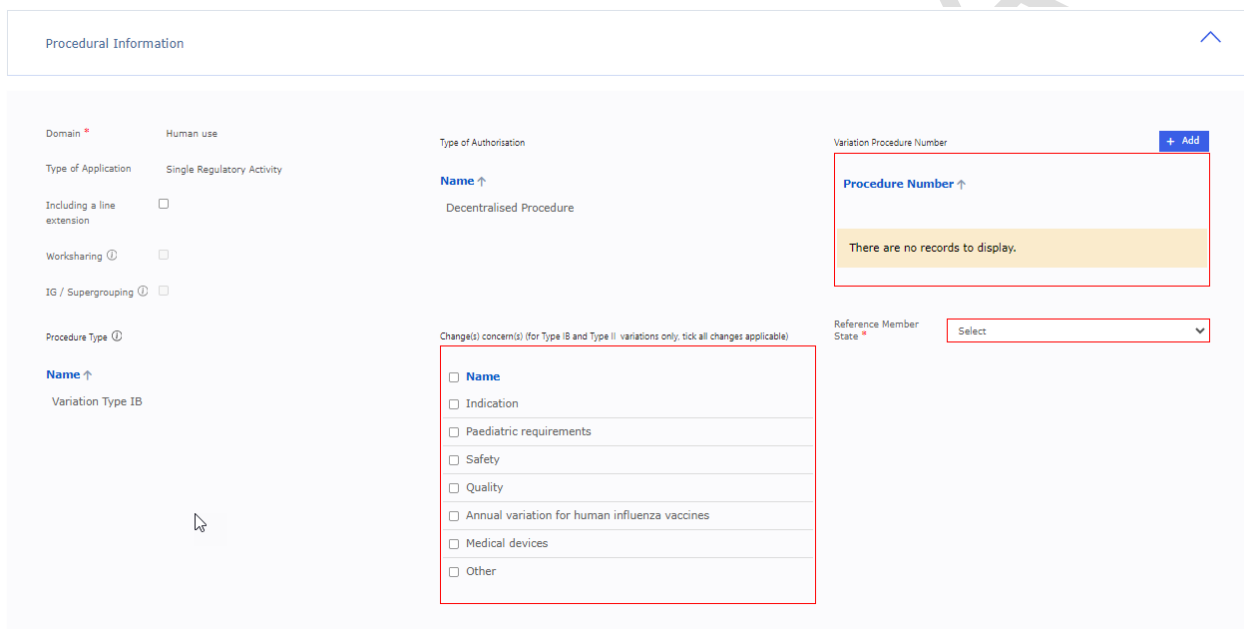
selected has for example more than 1 pharmaceutical forms, and your change impacts all 'medicinal products' you should select them all, but this does not mean that the work-sharing tick box will be ticked.

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

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

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

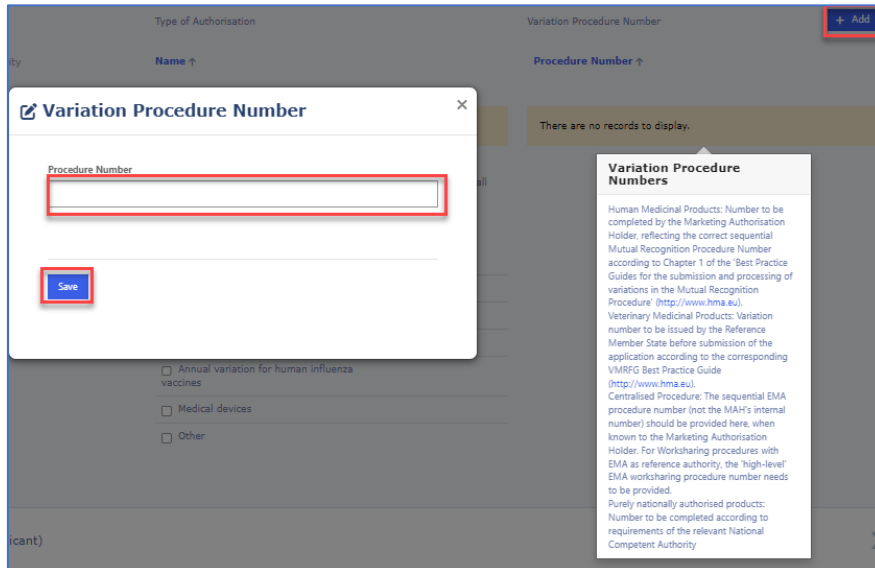
Figure 38 Example of non-CAP Type IB variation procedural information section



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

example for MRP variations, the MRP variation number should be added here. More information on the use of the variation procedure number can be found from the guidance [here](#).

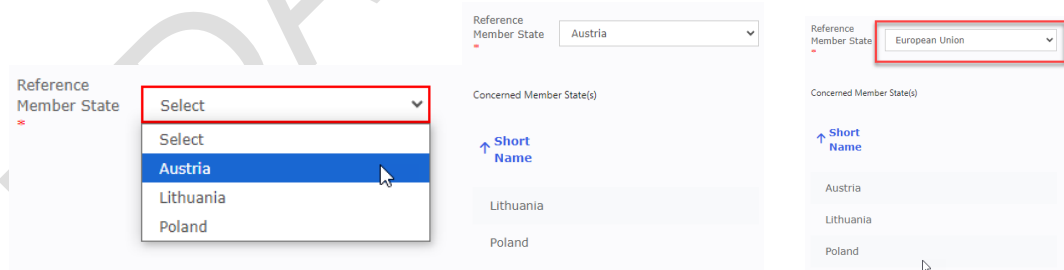
Figure 389. Variation Procedure Number



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

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

Figure 40. RMS/CMS selection

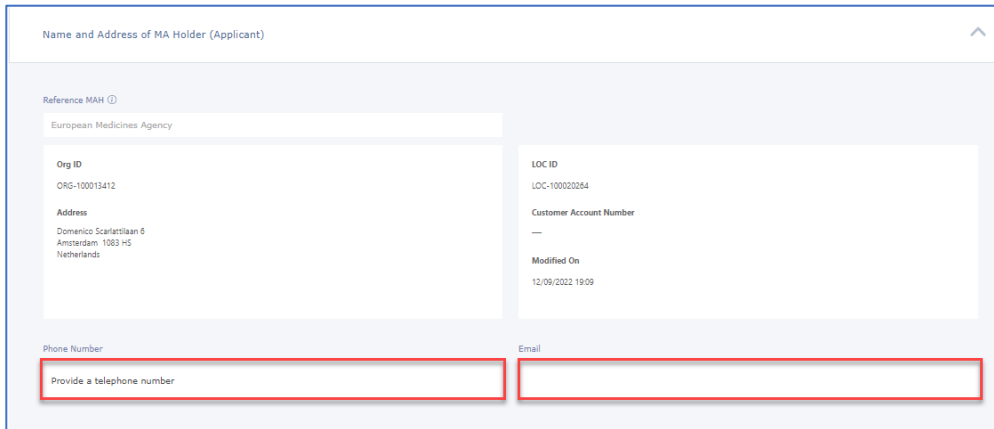


2.4.2. Name and Address of MA Holder (Applicant)

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

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

Figure 4139. Name and Address of MA Holder (Applicant)



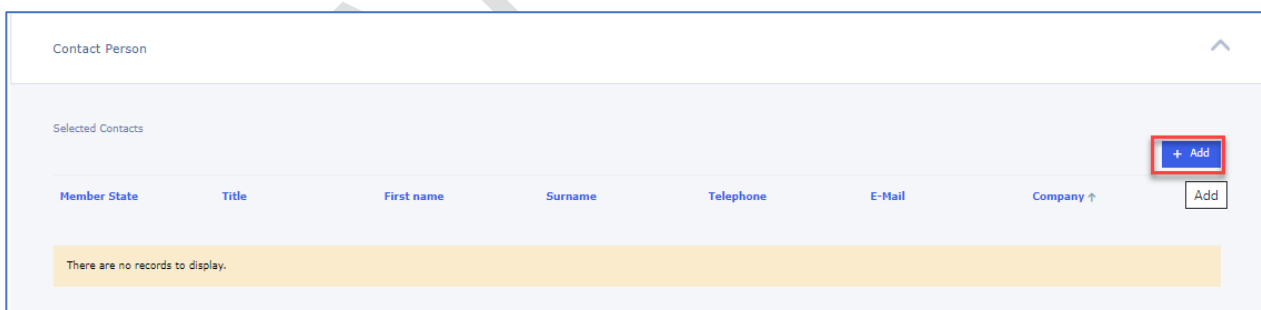
2.4.3. Contact Person

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

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

1. Click the **+ Add** button

Figure 402. Contact Person



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

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

For non-CAP applications, please use the multiselect member states function where needed or select each member state separately and provide the contact details where relevant.

Figure 412. Create Application Contact

Create Application Contact ×

<p>First name * <input type="text"/></p> <p>E-Mail * <input type="text"/></p> <p>Title <input type="text"/></p> <p>Company * <input type="text"/> 🔍</p>	<p>Surname * <input type="text"/></p> <p>Phone * <input type="text" value="Provide a telephone number"/></p> <p>Member State * <div style="border: 1px solid #ccc; padding: 2px;"> Denmark x France x </div> <ul style="list-style-type: none"> <li style="padding: 2px;">✓ Denmark <li style="padding: 2px;">✓ France <li style="padding: 2px;">🖱️ Netherlands </p>
---	--

Submit
Cancel

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

Figure 43. Lookup Records

Create Application Contact

First name *
Surname *

Select Company ×
 🔍

Choose one record and click Select to continue

	Organisation Name ↑	Full address	Organisation Id	Organisation Location
<input checked="" type="checkbox"/>	Terveysten Ja Hyvinvoinnin Laitos	Mannerheimintie 166 00300 Helsinki Helsinki-Uusimaa Finland	ORG-100019555	LOC-100039037
<input type="checkbox"/>	Terveysten Ja Hyvinvoinnin Laitos	Pl 30 00271 Helsinki Finland	ORG-100019555	LOC-100039039
<input type="checkbox"/>	Työterveyslaitos	Topeliuksenkatu 41b 00250 Helsinki Finland	ORG-100022861	LOC-100031573

Select
Cancel
Remove value

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

Figure 44. Contact person details



Create Application Contact x

First name *	Surname *
<input type="text"/>	<input type="text"/>
E-Mail *	Phone *
<input type="text"/>	<input type="text" value="Provide a telephone number"/>
Title	Member State
<input type="text"/>	<input type="text"/>
Company *	
<input type="text" value="Terveystieteiden tutkimuskeskus"/> <input type="button" value="x"/> <input type="button" value="Q"/>	
Org ID	LOC ID
ORG-100019555	LOC-100039037
Address	Customer Account Number
Mannerheimintie 166 Helsinki-Uusimaa 00300 Finland	—
	Modified On
	13/07/2022 14:07

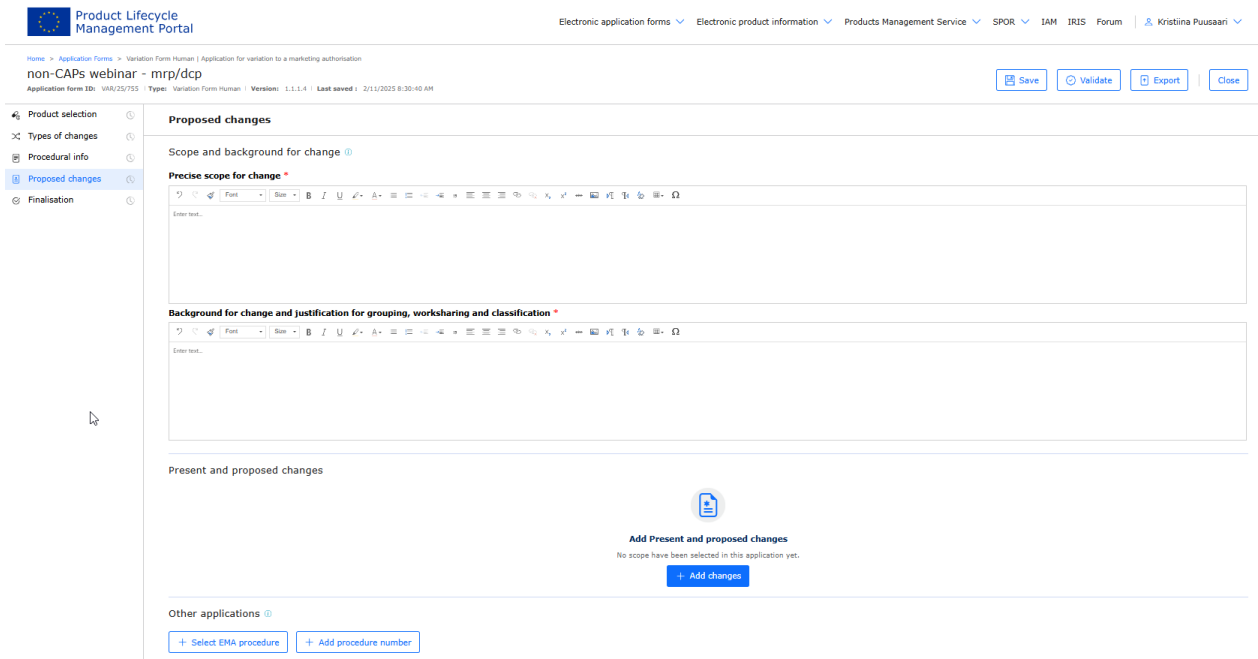
5. Click on the **Save** button and you will be taken back to the Procedural Information main page
6. Click on the **Save** button to save your changes. You may want to click on the **Validate** button to change the status of this section to **Completed**

2.5. Proposed Changes

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

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

Figure 425. Proposed Changes



2.5.1. Precise Scope and Background for Change

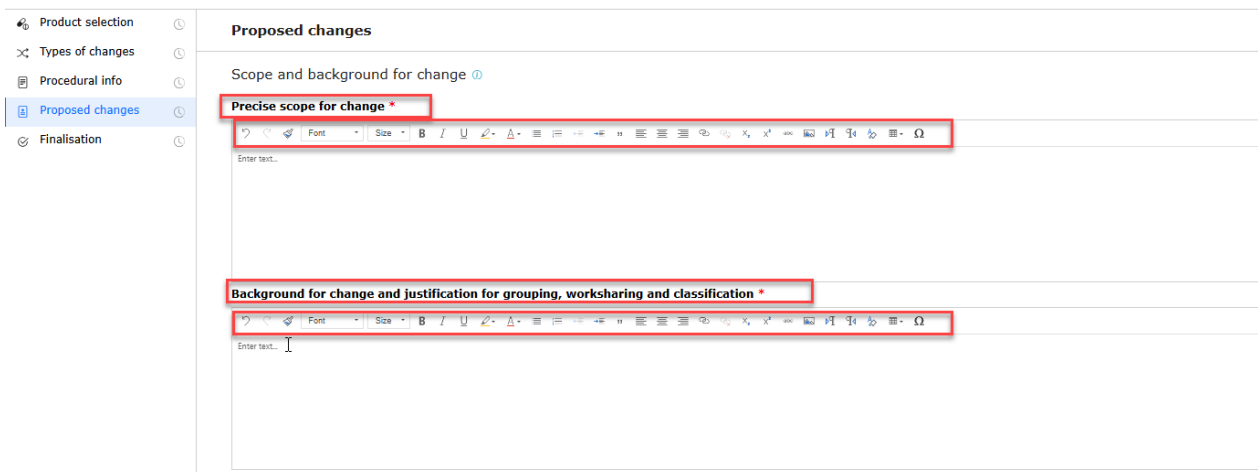
The actual changes that are being applied for should be stated in a concise way and a brief explanation provided of why the change is required.

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

1. Access an existing or create a new Application Form. See sections 2.1.2 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.

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

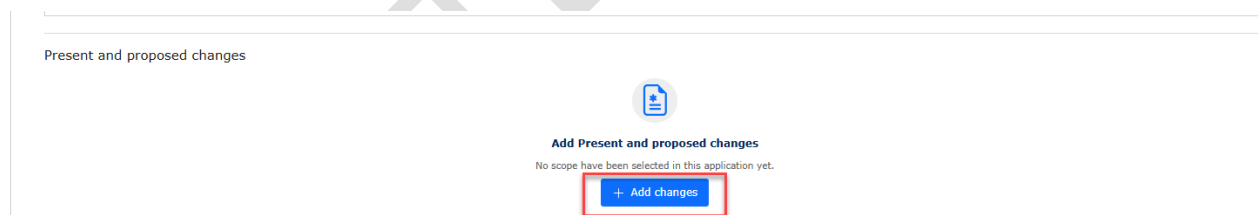
Figure 436. Precise Scope and Background for Change



2.5.2. Present and Proposed Changes

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

Figure 447. Proposed Changes



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

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

Figure 458. Selection of Scope and Medicinal Product

Select scope for proposed changes

Q Filter

B.II.b.1.a - Variation Type IAIN - 1

B.II.b.1.b - Variation Type IAIN - 1

B.II.b.1.e - Variation Type IB - 1

B.II.b.3.z - Variation Type IA - 1

B.II.b.4.a - Variation Type IA - 1

Cancel Done

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

Figure 49. Selection of Scope and Identifier (non-CAP)

Edit selected

Product packages Scope

Q Filter Add Package

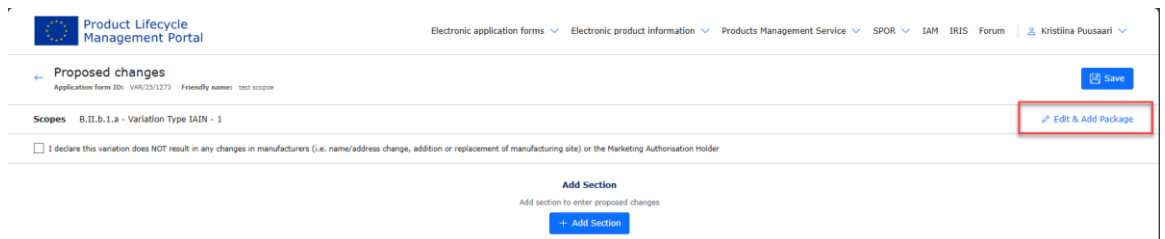
<input checked="" type="checkbox"/>	MA Number	MRP/CP Number	Package ID	Package size	Authorisation status	Pack description
<input checked="" type="checkbox"/>	Dantrium, 700000150791					
<input checked="" type="checkbox"/>	10476		3110019305		Valid	3750-36 -70 ml Type I glas hætteglas med brombutylgummiprop og aluminiumsforsøgelse med en polypropylen flip-off-hætte
<input checked="" type="checkbox"/>	10476		31036599		Valid	12 VIALS, 36 VIALS
<input checked="" type="checkbox"/>	DANTRIUM 100 mg, gélule, 600001683737					
<input checked="" type="checkbox"/>	34009 321 561 7		31214630		Valid - Transferred marketing authorisation	PCV/ALU BLISTER PACK OF 30 CAPSULES
<input checked="" type="checkbox"/>	34009 321 562 3		31214631		Valid - Transferred marketing authorisation	PCV/ALU BLISTER PACK OF 50 CAPSULES
<input checked="" type="checkbox"/>	Dantrium I.V., poeder voor injectievloeistof 20 mg, 700000151081					
<input checked="" type="checkbox"/>	RVG 08616		31400449		Valid - Renewed/Varied	

Cancel Done

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

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

Figure 50. Linking CAP packages to scopes



Product Lifecycle Management Portal

Electronic application forms | Electronic product information | Products Management Service | SPOR | IAM | IRIS | Forum | Kristiina Pussari

Proposed changes
Application form ID: VAR/25/1273 | Friendly name: test scope

Scopes B.II.b.1.a - Variation Type IAIN - 1

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

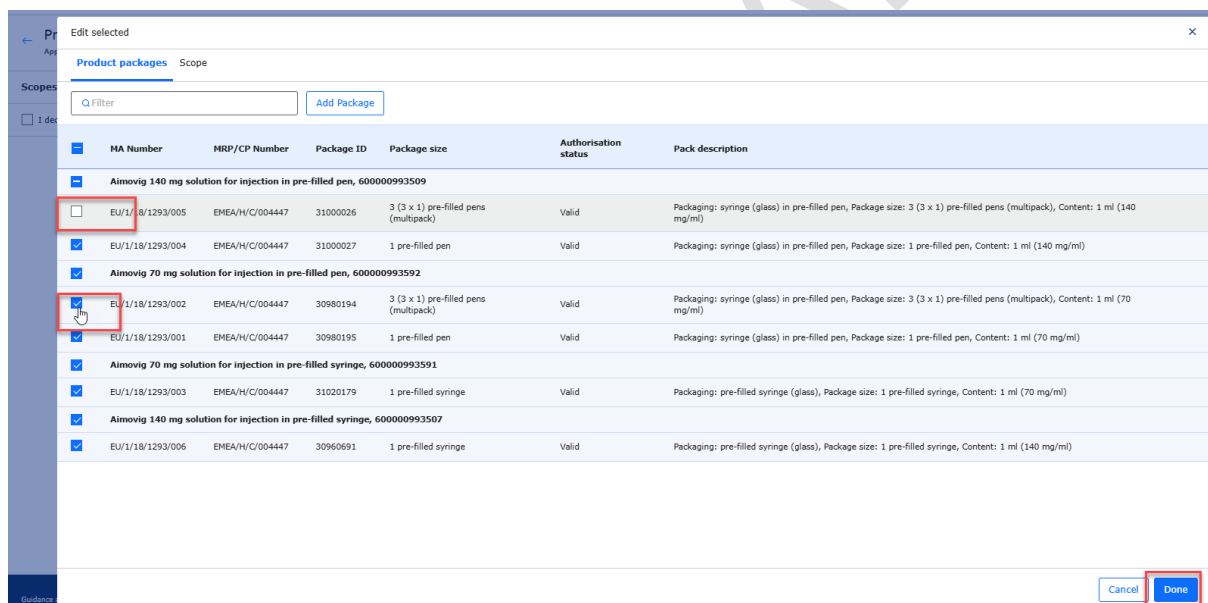
Add Section
Add section to enter proposed changes

[Add Section](#)

[Save](#) [Edit & Add Package](#)

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

Figure 51. Deselecting packaged medicinal products



Edit selected

Product packages Scope

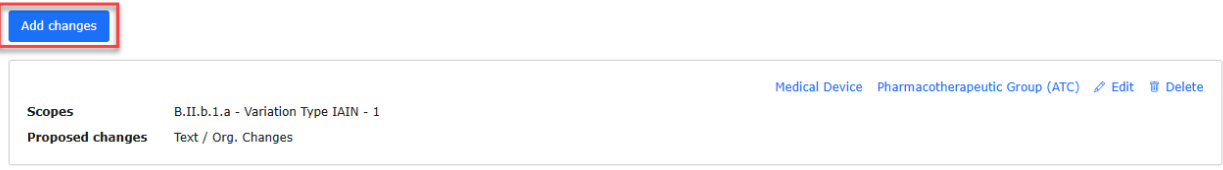
Filter Add Package

MA Number	MRP/CP Number	Package ID	Package size	Authorisation status	Pack description
Aimovig 140 mg solution for injection in pre-filled pen, 600000993509					
<input type="checkbox"/>	EU/1/18/1293/005	EMEA/H/C/004447	31000026	3 (3 x 1) pre-filled pens (multipack)	Valid Packaging: syringe (glass) in pre-filled pen, Package size: 3 (3 x 1) pre-filled pens (multipack), Content: 1 ml (140 mg/ml)
<input checked="" type="checkbox"/>	EU/1/18/1293/004	EMEA/H/C/004447	31000027	1 pre-filled pen	Valid Packaging: syringe (glass) in pre-filled pen, Package size: 1 pre-filled pen, Content: 1 ml (140 mg/ml)
Aimovig 70 mg solution for injection in pre-filled pen, 600000993592					
<input checked="" type="checkbox"/>	EU/1/18/1293/002	EMEA/H/C/004447	30980194	3 (3 x 1) pre-filled pens (multipack)	Valid Packaging: syringe (glass) in pre-filled pen, Package size: 3 (3 x 1) pre-filled pens (multipack), Content: 1 ml (70 mg/ml)
<input checked="" type="checkbox"/>	EU/1/18/1293/001	EMEA/H/C/004447	30980195	1 pre-filled pen	Valid Packaging: syringe (glass) in pre-filled pen, Package size: 1 pre-filled pen, Content: 1 ml (70 mg/ml)
Aimovig 70 mg solution for injection in pre-filled syringe, 600000993591					
<input checked="" type="checkbox"/>	EU/1/18/1293/003	EMEA/H/C/004447	31020179	1 pre-filled syringe	Valid Packaging: pre-filled syringe (glass), Package size: 1 pre-filled syringe, Content: 1 ml (70 mg/ml)
Aimovig 140 mg solution for injection in pre-filled syringe, 600000993507					
<input checked="" type="checkbox"/>	EU/1/18/1293/006	EMEA/H/C/004447	30960691	1 pre-filled syringe	Valid Packaging: pre-filled syringe (glass), Package size: 1 pre-filled syringe, Content: 1 ml (140 mg/ml)

Cancel Done

- c. If all changes concern all products/presentations, simply leave all packaged medicinal products selected. You can repeat this step to link the changes in present and proposed to a particular scope/product combination as many times as necessary.
- d. You **must** select **at least one scope** and **one packaged medicinal product for each combination**. All listed scopes must be selected in the form and linked to at least one packaged medicinal product (i.e. to at least one MA number).
5. Select the related Medicinal Product(s)/presentations and click **Done** to return to the Present and Proposed to add details of the changes or to continue filling other sections. If you have multiple changes/scopes that impact only part of the selected products, repeat this change to indicate the changes linked to those scopes.
6. Previously added sections in the present and proposed section are listed in the main view. If you have multiple changes/scopes that impact only part of the products selected, repeat this change to indicate the changes linked to those scopes. To repeat the step click on **Add Changes**. The selected scopes and products will be shown and can be edited.

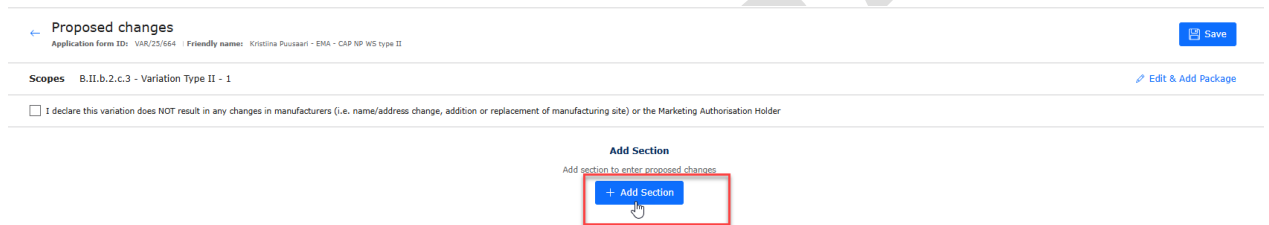
Present and proposed changes



2.5.2.2. Present and Proposed Text Changes

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

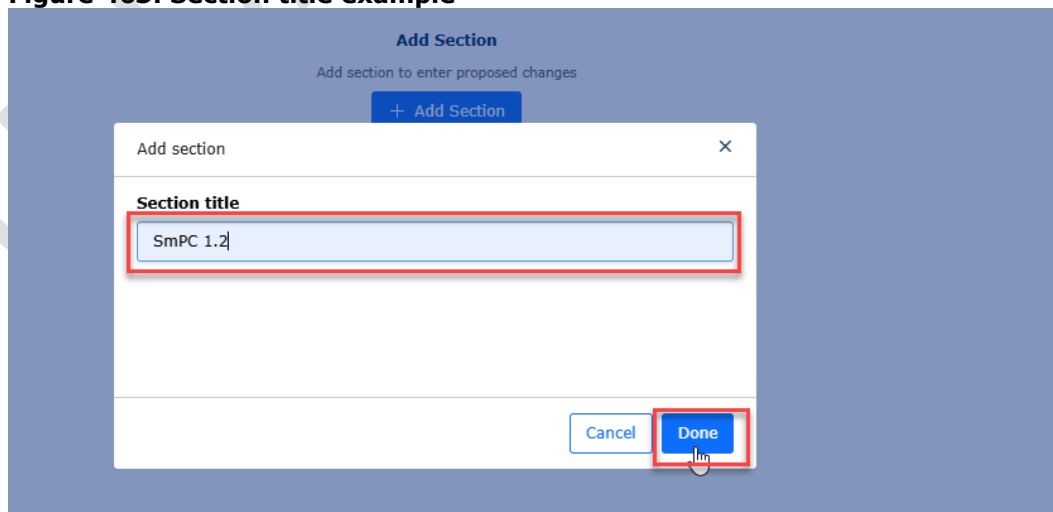
Figure 52. Present and Proposed scope selection



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

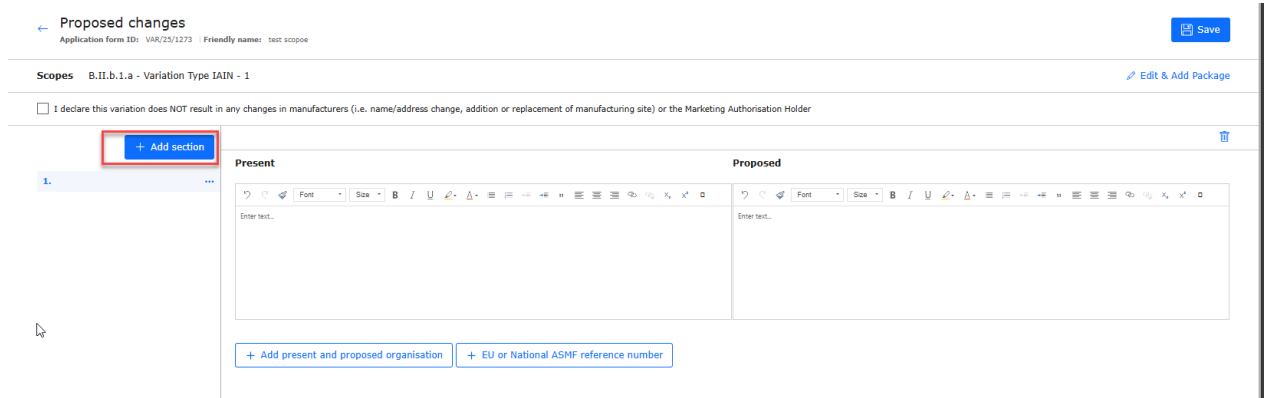
If you do not wish to provide a section title, simply click 'Done' to proceed to fill in the Present and Proposed fields.

Figure 463. Section title example



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

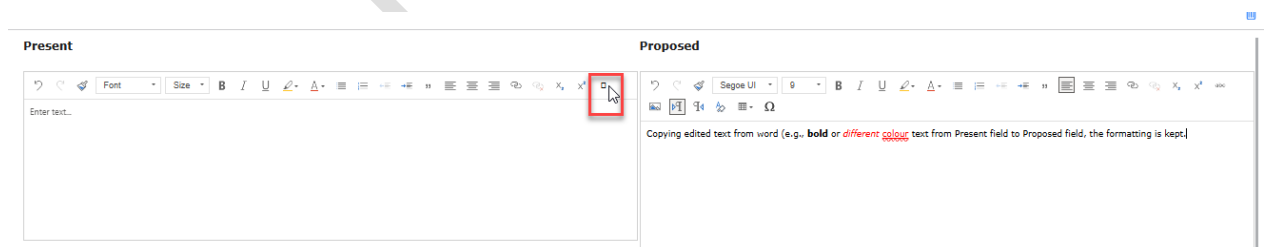
Figure 54. Adding sections



The screenshot shows the 'Proposed changes' interface. At the top, there is a 'Save' button. Below it, the 'Scopes' section is labeled 'B.II.b.1.a - Variation Type IAIN - 1'. A checkbox is present with the text 'I declare this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder'. A '+ Add section' button is highlighted with a red box. Below this, there are two text input fields labeled 'Present' and 'Proposed', each with a rich text editor toolbar. At the bottom, there are two buttons: '+ Add present and proposed organisation' and '+ EU or National ASMF reference number'.

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

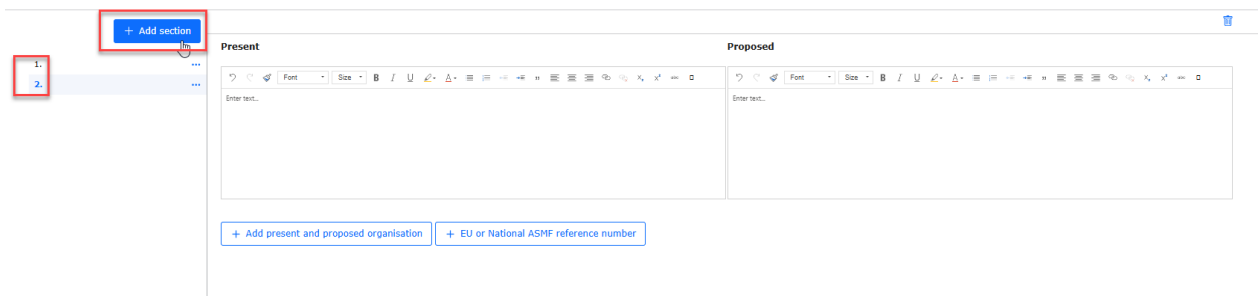
Figure 55. Editing Present and Proposed fields



The screenshot shows the 'Present' and 'Proposed' text input fields. The 'Present' field has a rich text editor toolbar with a small square icon at the end, which is highlighted with a red box. The 'Proposed' field has a similar toolbar and contains the text 'Copying edited text from word (e.g., **bold** or *different colour* text from Present field to Proposed field, the formatting is kept)'. The text in the 'Proposed' field is formatted to match the original source document.

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

Figure 56. Add sections

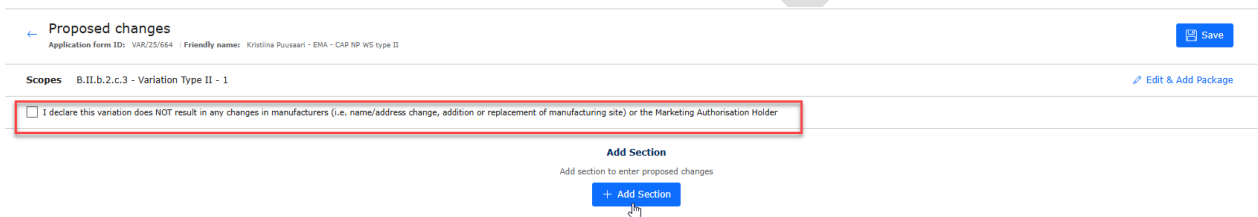


The screenshot shows a web interface with two main text input areas labeled 'Present' and 'Proposed'. Each area has a rich text editor toolbar. Above the 'Present' editor is a blue button labeled '+ Add section'. Below both editors are two more blue buttons: '+ Add present and proposed organisation' and '+ EU or National ASMF reference number'. On the left side, there is a vertical list with items numbered 1 and 2, and a red box highlights the '+ Add section' button.

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

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

Figure 57. Mandatory use of OMS For CAPs



The screenshot shows the 'Proposed changes' section of the eAF. At the top, it displays 'Application form ID: VAR/25/664' and 'Friendly name: Kristina Puusari - EMA - CAP NP WS type II'. Below this, the 'Scopes' are listed as 'B.II.b.2.c.3 - Variation Type II - 1'. A red box highlights a checkbox with the text: 'I declare this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder'. Below the checkbox is a blue button labeled '+ Add Section' with the text 'Add section to enter proposed changes' above it.

2.5.2.3. Organisation Details

NOTE: The eAF team is aware of number of various issues affecting the OMS integration with the PLM Portal eAF. There are cases where it is not possible to select/find the correct organisation in the eAF although OMS is up to date. In case of an OMS issue, please raise a [service desk ticket](#) with detailed description of the issue and we will review if it is possible to solve the issue. In some cases, the issues are derived from OMS data used in IRIS and it may not be always possible to solve these issues, in these cases, we may have to ask you to revert back to using the interactive pdf eAF to avoid any delays to the application. We are actively trying to solve these issues, however, some require deep analysis and complex technical implementation which will continue in 2025.

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

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

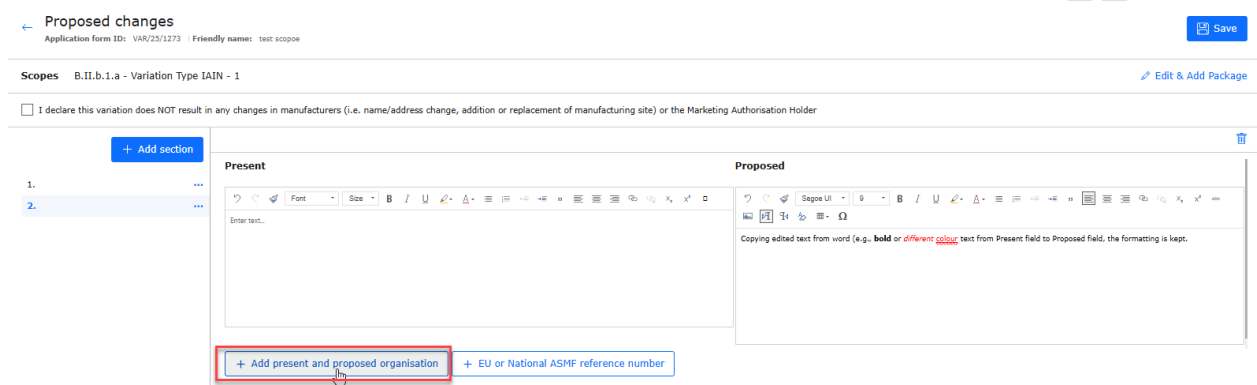
Please note: In order to ensure you do not to lose any changes, ideally to ensure that you **select organisations that are impacted from OMS as the first step**. Changes added to the Present and

Proposed fields may **be lost** if you enter these first and then add an organisation details using the **Add** button to select the Present and Proposed organisations.


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

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

Figure 47. OMS changes

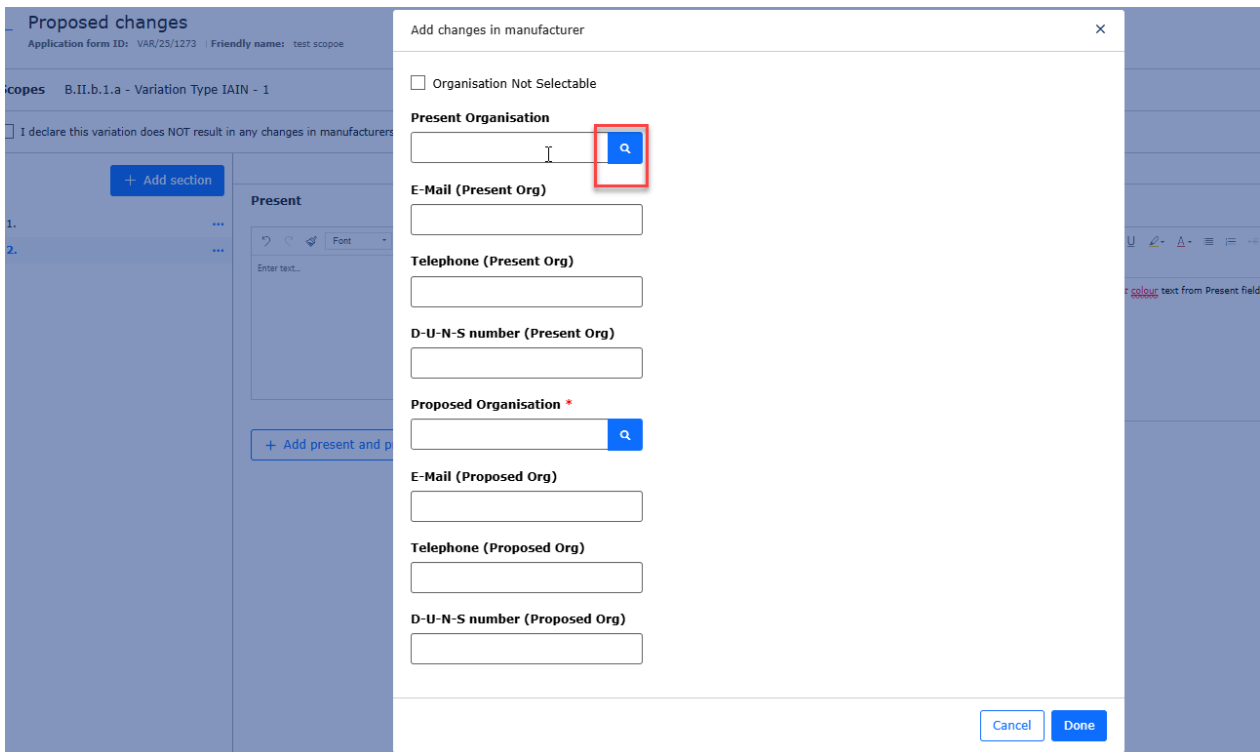


The screenshot shows the 'Proposed changes' interface. At the top, there is a 'Proposed changes' header with a back arrow, application form ID (VAR/25/1273), and friendly name (test scope). A 'Save' button is in the top right. Below the header, the 'Scopes' section shows 'B.II.b.1.a - Variation Type IAIN - 1' and an 'Edit & Add Package' link. A checkbox is present with the text: 'I declare this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder'. The main area is divided into two text editors: 'Present' and 'Proposed'. The 'Present' editor has a red box around the '+ Add present and proposed organisation' button. The 'Proposed' editor shows a message: 'Copying edited text from word (e.g., bold or different colour) text from Present field to Proposed field, the formatting is kept.'

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

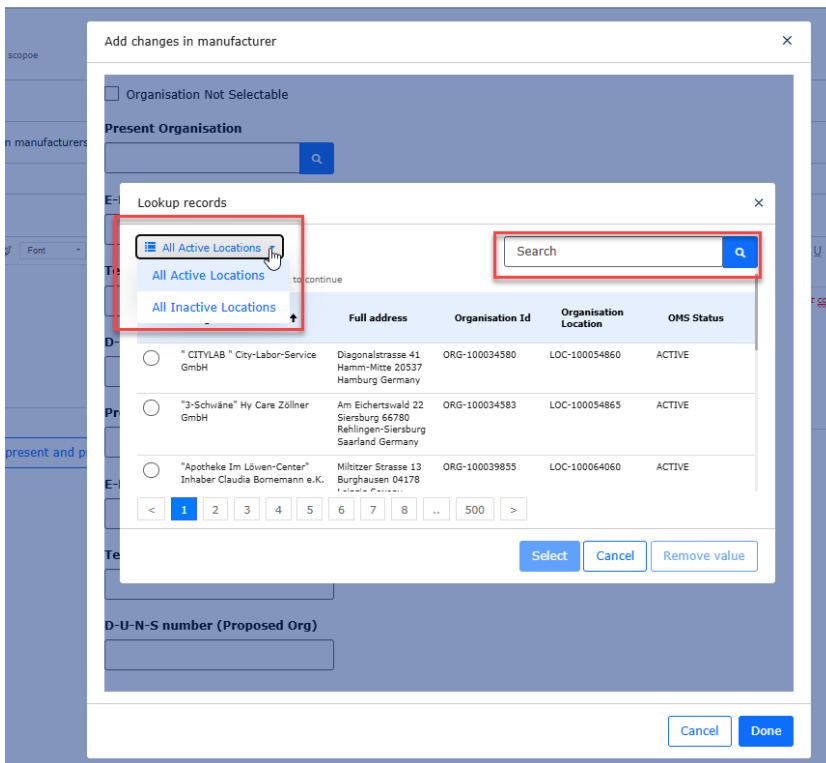
If the organisation is not found from OMS, it is possible to manually enter the organisation details on the present organisation.

Figure 48. Proposed Changes - Add/Edit Organisation



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

Figure 49. Select Present Organisation



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

Figure 50. Organisation Not Selectable



Figure 51. Data of Not Selectable Organisation



Add changes in manufacturer

Organisation Not Selectable

Organisation Name *

Address Line 1 *

Address line 2

Address line 3

Address line 4

City/Locality/Town/Village *

Post code

State

Cancel Done

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

Figure 52. Proposed Organisation



Add changes in manufacturer

Country *

Proposed Organisation *

E-Mail (Present Org)

Telephone (Present Org)

D-U-N-S number (Present Org)

E-Mail (Proposed Org)

Telephone (Proposed Org)

D-U-N-S number (Proposed Org)

Cancel Done

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

Figure 53. Present and Proposed Section

Add changes in manufacturer

Country *

Lookup records

Search: european medicines agency

Choose one record and click Select to continue

✓	Organisation Name ↑	Full address	Organisation Id	Organisation Location
<input type="radio"/>	European Medicines Agency	P. O. Box 71010 1008 BA Amsterdam Netherlands	ORG-100013412	LOC-100020260
<input checked="" type="radio"/>	European Medicines Agency	Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands	ORG-100013412	LOC-100020264
<input type="radio"/>	European Medicines Agency's	Gairinės g. 27 Vilnius 02200 Lithuania	ORG-100053363	LOC-100094289

Buttons: Select, Cancel, Remove value

D-U-N-S number (Proposed Org)

Buttons: Cancel, Done

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

Figure 54. Present and Proposed Value(s)

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

+ Add section

1. ...

2. ...

Present

Enter text...

Proposed

Copying edited text from word (e.g., bold or different colour) text from Present field to Proposed field, the formatting is kept.

Present Organisation	Proposed Organisation
Organisation Name: European Medicines Agency	Organisation Name: European Medicines Agency
Organisation Location: LOC-100020260	Organisation Location: LOC-100020264
Organisation ID: ORG-100013412	Organisation ID: ORG-100013412
Address: P. O. Box 71010 1008 BA Amsterdam Netherlands	Address: Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands
Parent organisation: European Medicines Agency	Parent organisation: European Medicines Agency
Modified on: 2024-11-20T10:41:09Z	Modified on: 2025-01-14T16:27:02Z
Email address:	Email address:
Telephone number:	Telephone number:
D-U-N-S number:	D-U-N-S number:

+ Add present and proposed organisation

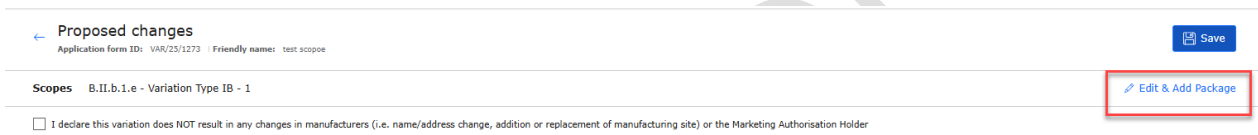
2.5.3. Add Package to an Existing Product

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

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

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

Figure 55. Add package



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



product is **automatically** selected. This automatically selected packaged medicinal product needs to be **unselected** after the new package has been added.

Edit selected X

Product packages Scope

Q Filter Add Package

<input checked="" type="checkbox"/>	MA Number	MRP/CP Number	Package ID	Package size	Authorisation status	Pack description
<input checked="" type="checkbox"/>	Aimovig 140 mg solution for injection in pre-filled pen, 600000993509					
<input checked="" type="checkbox"/>	EU/1/18/1293/005	EMEA/H/C/004447	31000026	3 (3 x 1) pre-filled pens (multipack)	Valid	Packaging: syringe (glass) in pre-filled pen, Package size: 3 (3 x 1) pre-filled pens (multipack), Content: 1 ml (140 mg/ml)
<input checked="" type="checkbox"/>	EU/1/18/1293/004	EMEA/H/C/004447	31000027	1 pre-filled pen	Valid	Packaging: syringe (glass) in pre-filled pen, Package size: 1 pre-filled pen, Content: 1 ml (140 mg/ml)
<input checked="" type="checkbox"/>	Aimovig 70 mg solution for injection in pre-filled pen, 600000993592					
<input checked="" type="checkbox"/>	EU/1/18/1293/002	EMEA/H/C/004447	30980194	3 (3 x 1) pre-filled pens (multipack)	Valid	Packaging: syringe (glass) in pre-filled pen, Package size: 3 (3 x 1) pre-filled pens (multipack), Content: 1 ml (70 mg/ml)
<input checked="" type="checkbox"/>	EU/1/18/1293/001	EMEA/H/C/004447	30980195	1 pre-filled pen	Valid	Packaging: syringe (glass) in pre-filled pen, Package size: 1 pre-filled pen, Content: 1 ml (70 mg/ml)
<input checked="" type="checkbox"/>	Aimovig 70 mg solution for injection in pre-filled syringe, 600000993591					
<input checked="" type="checkbox"/>	EU/1/18/1293/003	EMEA/H/C/004447	31020179	1 pre-filled syringe	Valid	Packaging: pre-filled syringe (glass), Package size: 1 pre-filled syringe, Content: 1 ml (70 mg/ml)
<input checked="" type="checkbox"/>	Aimovig 140 mg solution for injection in pre-filled syringe, 600000993507					
<input checked="" type="checkbox"/>	EU/1/18/1293/006	EMEA/H/C/004447	30960691	1 pre-filled syringe	Valid	Packaging: pre-filled syringe (glass), Package size: 1 pre-filled syringe, Content: 1 ml (140 mg/ml)

Cancel Done

7.

Pending Variation Form Human / Version: 1.0.1.14 / Application for variation to a marketing authorisation

Proposed Changes > Present and Proposed Value(s) / VAR/24/1313 Last Saved: 17/07/2024 13:15

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

Column visibility Filter

<input checked="" type="checkbox"/>	Product Name	MRP / CP Number	MA Number	Authorisation Country	PMS Id
<input checked="" type="checkbox"/>	CARVATI... cells dispersion for infusion	EMEA/H/C/000095	EU/1/2...8	European Union	600006099961

Showing 1 to 1 of 1 entries 1 row selected

Selected Packaged Medicinal Product(s)

Column visibility Refresh Filter Add Package

<input checked="" type="checkbox"/>	MA Number	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status
<input checked="" type="checkbox"/>	EU/1/22/1648/001	EMEA/H/C/005095	8140001	1 bag	Packaging: bag (EVA), Package size: 1 bag, Content: 30 ml or 70 ml	Valid

Showing 1 entries 1 row selected

Save Close

- Click the option "add package", this will open a pop up window to include the details for the new pack size
- Select the 'Parent Medicinal Product'. If you have more than 1 medicinal product and you wish to add a package to each medicinal product, you will need to repeat this step. It is not possible to select multiple medicinal products at one go. Please note that it is not necessary to select



the medicinal product from the list before you open the pop up, the medicinal product for which the package will be added is the one selected in the pop-up.



Add Package

×

Parent Medicinal Product *

CARV... dispersion for infusion

MA Number *

Pack Size *

Submit

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

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

Add Package

Parent Medicinal Product *

CARV... dispersion for infusion

MA Number *

EU/1/22/1648/002

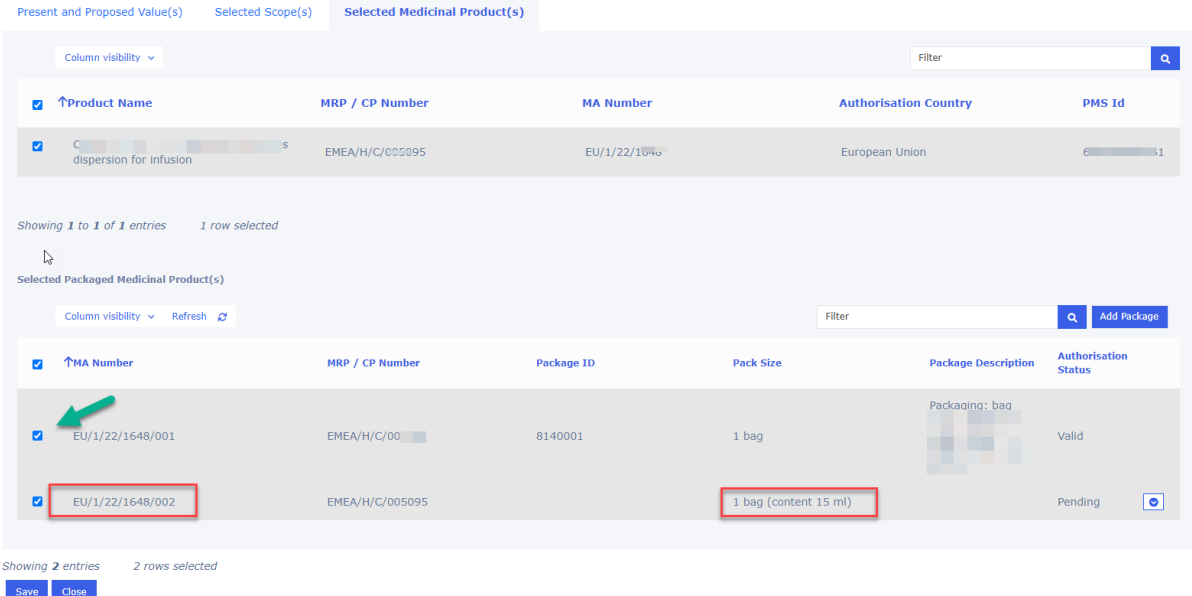
Pack Size *

1 bag (content 15 ml)

Submit

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

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



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

Column visibility Filter

Product Name	MRP / CP Number	MA Number	Authorisation Country	PMS Id
Carvymkti 3.2 x 10 ⁶ - 1 x 10 ⁸ cells dispersion for infusion	EMA/H/C/005095	EU/1/22/1648/001	European Union	600000001

Showing 1 to 1 of 1 entries 1 row selected

Selected Packaged Medicinal Product(s)

Column visibility Refresh Filter Add Package

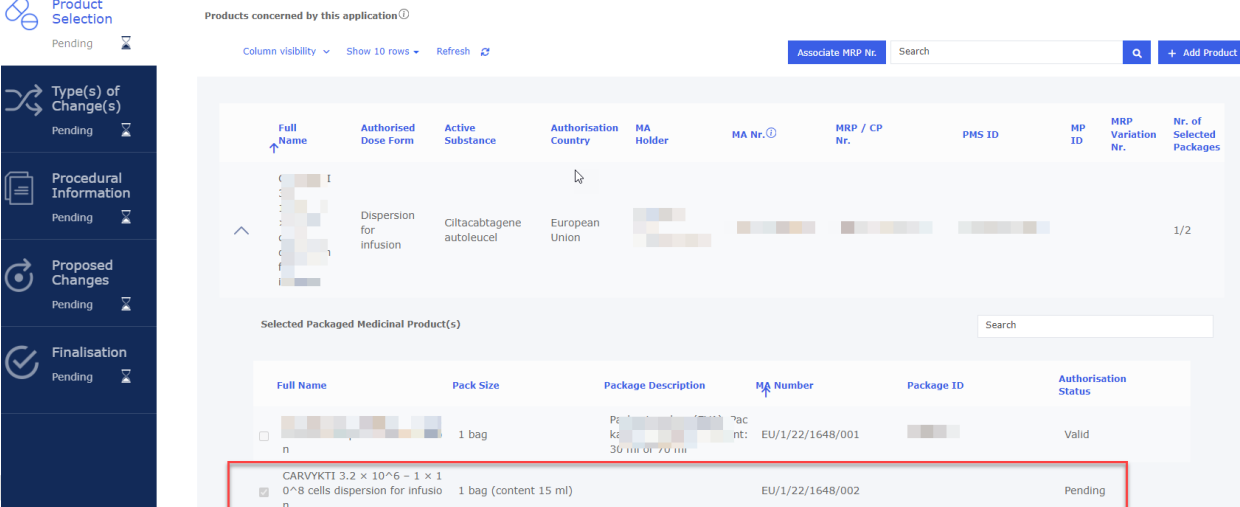
MA Number	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status
EU/1/22/1648/001	EMA/H/C/005095	8140001	1 bag	Packaging: bag	Valid
EU/1/22/1648/002	EMA/H/C/005095		1 bag (content 15 ml)		Pending

Showing 2 entries 2 rows selected

Save Close

14. Proceed to save the change.

15. You can now navigate back to the product selection section where you can see the new 'pending' entry added.



Product Selection Pending

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.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
Carvymkti 3.2 x 10 ⁶ - 1 x 10 ⁸ cells dispersion for infusion	Dispersion for infusion	Ciltacabtagene autoleucel	European Union							1/2

Selected Packaged Medicinal Product(s)

Search

Full Name	Pack Size	Package Description	MA Number	Package ID	Authorisation Status
Carvymkti 3.2 x 10 ⁶ - 1 x 10 ⁸ cells dispersion for infusion	1 bag	Packaging: bag	EU/1/22/1648/001		Valid
Carvymkti 3.2 x 10 ⁶ - 1 x 10 ⁸ cells dispersion for infusion	1 bag (content 15 ml)		EU/1/22/1648/002		Pending

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

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



2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

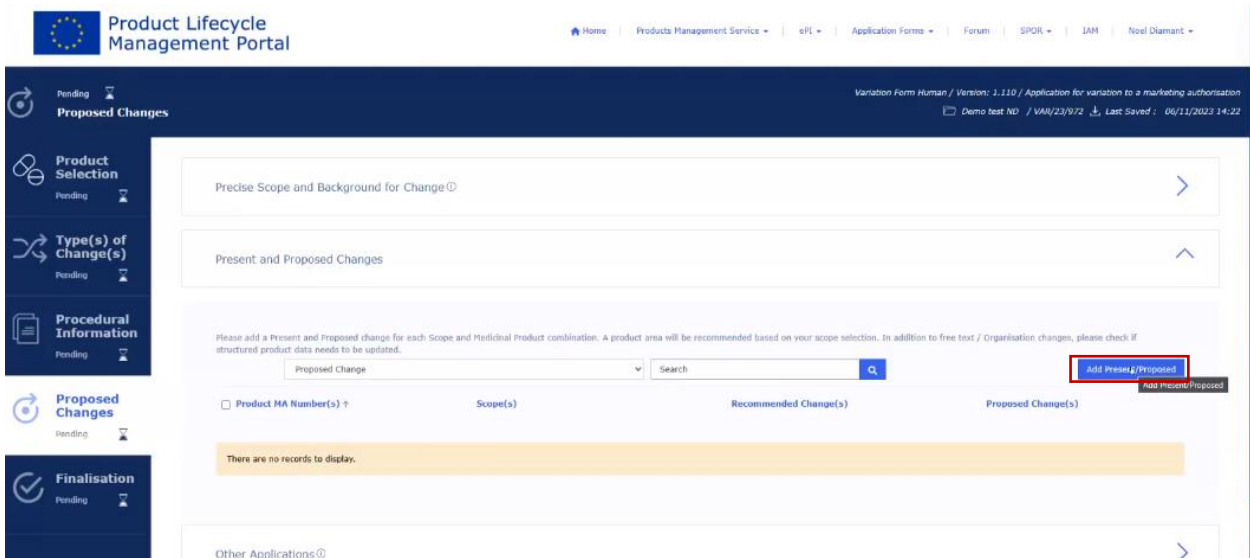
Active Substance					
Oc...					
MA Number(s) ⁸	Full name ²¹	MA Holder name	Member state	Pharmaceutical Form ²²	
EU/1/1...	... solvent for solution for		European Union	Powder and solvent for solution for injection	
EU/1/1...	... injection		European Union	Powder and solvent for solution for injection	

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

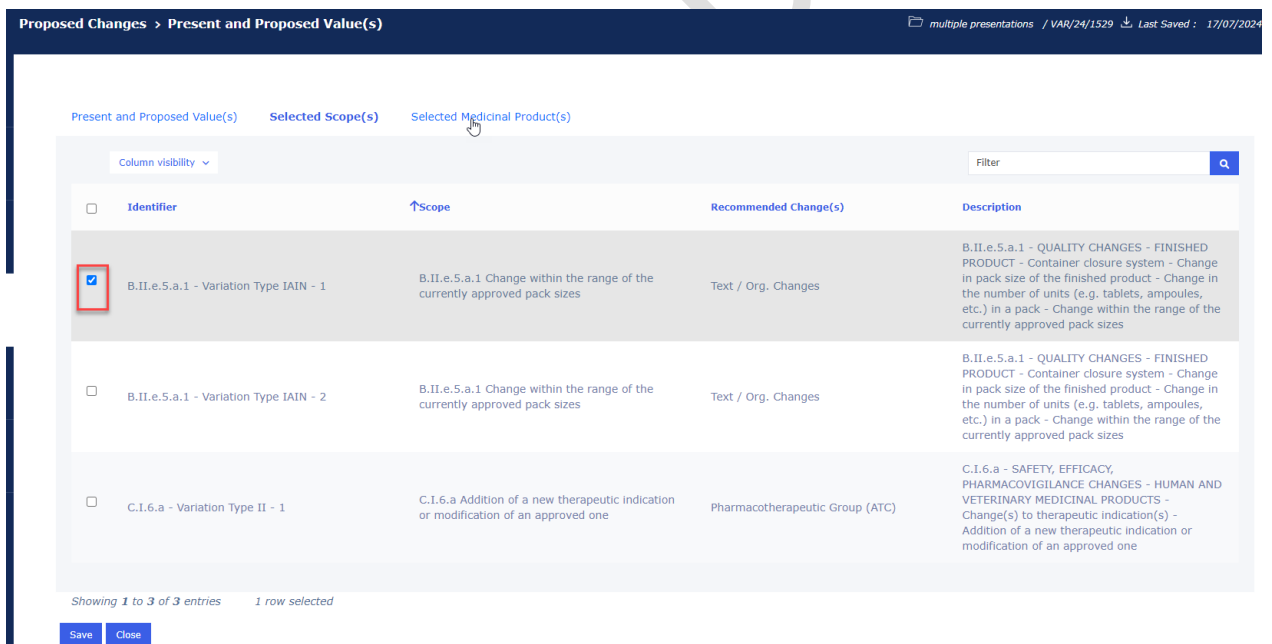
Scope	B.II.e.5.a.1 - Variation Type IAIN - 1	
Product(s) Package(s)	Kc... wder and solvent for solution for injection	<i>all packages listed in section 2 for the product</i>
	Present ^{9,10}	Proposed ^{9,10}
Text	details on the existing presentations	new presentation (multipack) Add details to present and proposed fields as per normal
	Present ^{9,10}	Proposed ^{9,10}
	EU/1/15...76/0XX	
	Package	These fields contain the information from the MA number and Pack size fields in the pop up window
	- MA number: EU/1/15...76/0XX - Description: 1 + 1 (new multipack)	
<input checked="" type="checkbox"/> I declare this variation does NOT result in any changes in manufacturers (i.e. name/ address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder		

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

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

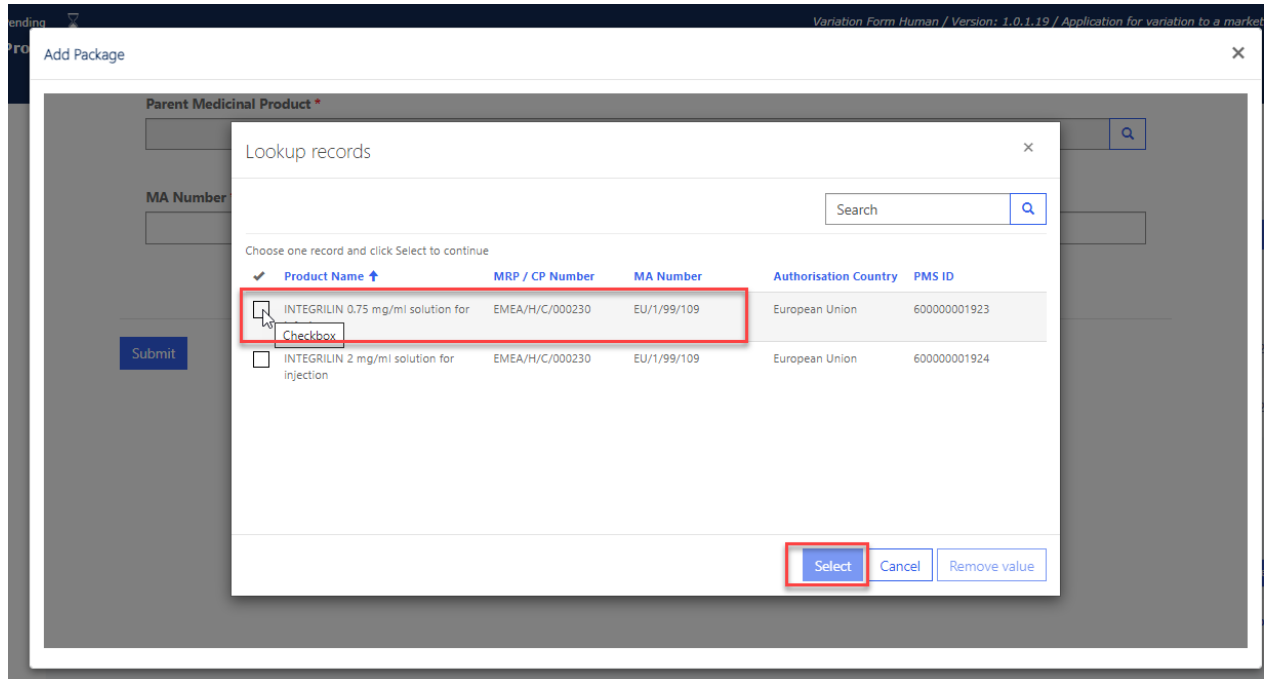


3. Fill in details in 'Present and Proposed Value(s)' tab
4. Select **1 scope** (for example B.II.e.5.a) **at the time** to link with the new pack size (presentation). The other scopes will need to be linked to presentations in separate, repeated steps.



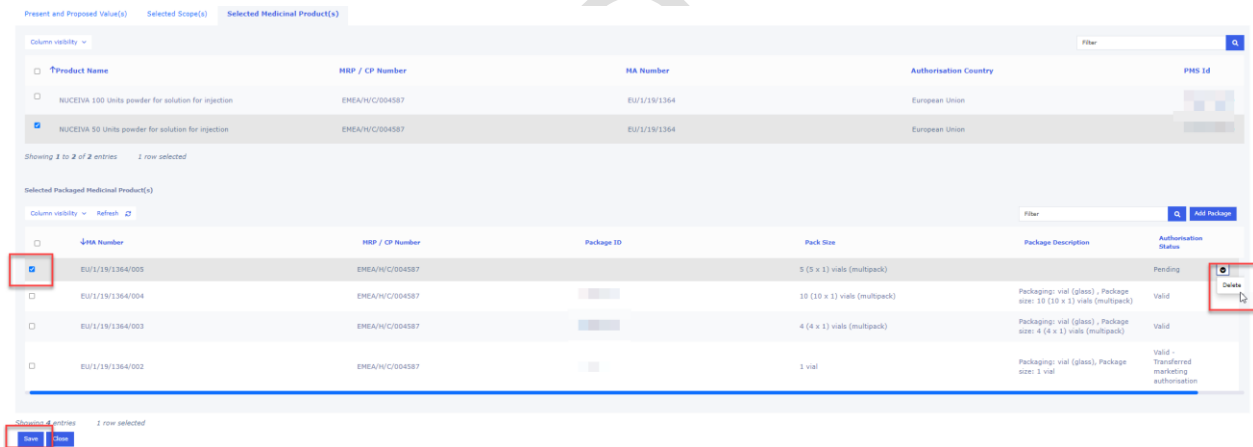
Identifier	Scope	Recommended Change(s)	Description
<input checked="" type="checkbox"/> B.II.e.5.a.1 - Variation Type IAIN - 1	B.II.e.5.a.1 Change within the range of the currently approved pack sizes	Text / Org. Changes	B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
<input type="checkbox"/> B.II.e.5.a.1 - Variation Type IAIN - 2	B.II.e.5.a.1 Change within the range of the currently approved pack sizes	Text / Org. Changes	B.II.e.5.a.1 - QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes
<input type="checkbox"/> C.I.6.a - Variation Type II - 1	C.I.6.a Addition of a new therapeutic indication or modification of an approved one	Pharmacotherapeutic Group (ATC)	C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one

5. Select the tab "Selected Medicinal Product(s)."
6. Following the updated design, it is recommended to select the medicinal product in the pop-up window instead of selecting it on the list to avoid selecting different medicinal product from the



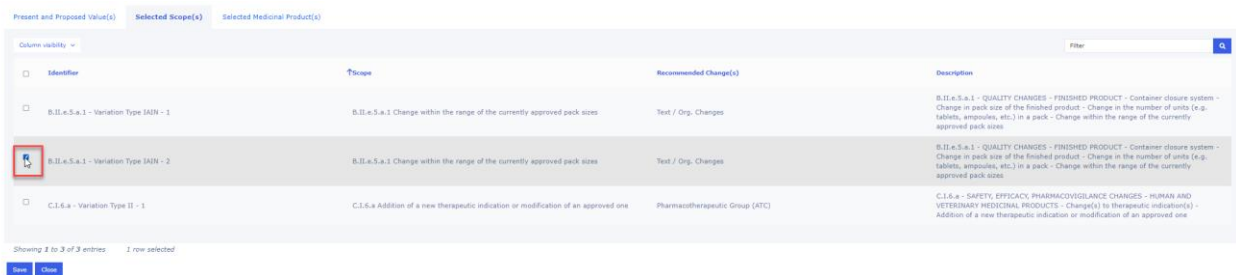
11. You can now see the newly added pack size in the list of packaged medicinal products.

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



13. Proceed to save the change.

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



Product Selection

Products concerned by this application

Full Name	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
[Redacted]	Dispersion for infusion	Giltacabtagene autoleucel	European Union	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	1/2

Selected Packaged Medicinal Product(s)

Full Name	Pack Size	Package Description	MA Number	Package ID	Authorisation Status
[Redacted]	1 bag	Per [Redacted] Pac [Redacted] ke [Redacted] nt: 30 ml or 70 ml	EU/1/22/1648/001	[Redacted]	Valid
CARVYKTI 3.2 × 10 ⁶ – 1 × 10 ⁸ cells dispersion for infusio	1 bag (content 15 ml)		EU/1/22/1648/002		Pending

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

2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

Active Substance	
Oct [Redacted] [Redacted] g alfa	
MA Number(s) ⁸	Full name ²¹
EU/1/1 [Redacted] [Redacted]	[Redacted] solvent for solution for
EU/1/1 [Redacted] [Redacted]	[Redacted] solvent for solution for injection
MA Holder name	Member state
[Redacted]	European Union
[Redacted]	European Union
Pharmaceutical Form ²²	
Powder and solvent for solution for injection	
Powder and solvent for solution for injection	

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



Scope	B.II.e.5.a.1 - Variation Type IAIN - 1	
Product(s) Package(s)	K... powder and solvent for solution for injection <i>all packages listed in section 2 for the product</i>	
	Present ^{9,10}	Proposed ^{9,10}
Text	details on the existing presentations	new presentation (multipack) Add details to present and proposed fields as per normal
	Present ^{9,10}	Proposed ^{9,10}
	EU/1/15.../76/0XX	
	Package	These fields contain the information from the MA number and Pack size fields in the pop up window
	- MA number: EU/1/15.../76/0XX - Description: 1 + 1 (new multipack)	
<input checked="" type="checkbox"/> I declare this variation does NOT result in any changes in manufacturers (i.e. name/ address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder		

2.5.3.3. Multiple change

2.5.3.3.1. Duplicating the Present and Proposed fields

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

2.5.3.3.2. Linking of the organisations to the text changes

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

2.5.3.4. Structured changes

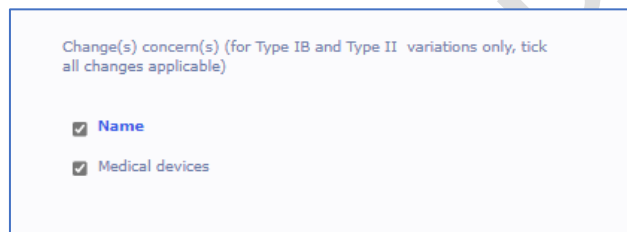
Note that currently 'Recommended Changes' column may indicate **non-relevant area of changes**, due to scopes being linked to many different types of changes. This will be addressed and improved in future releases.

2.5.3.5. Medical Device(s)

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

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

Figure 56. Medical Device Box



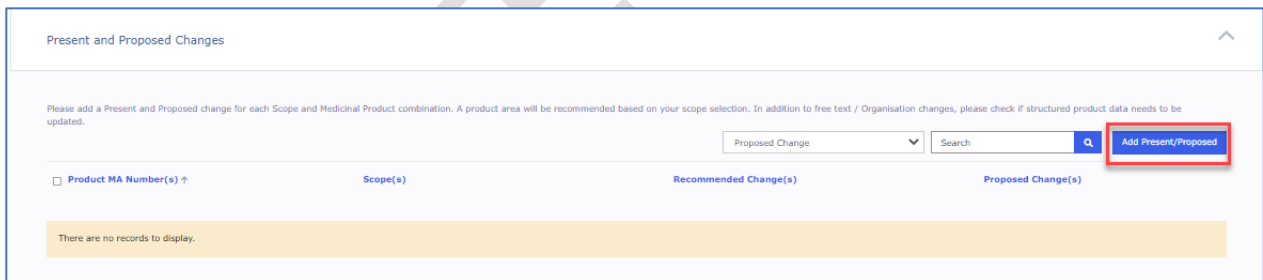
Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

Name

Medical devices

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

Figure 57. Add Present/Proposed Changes



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.

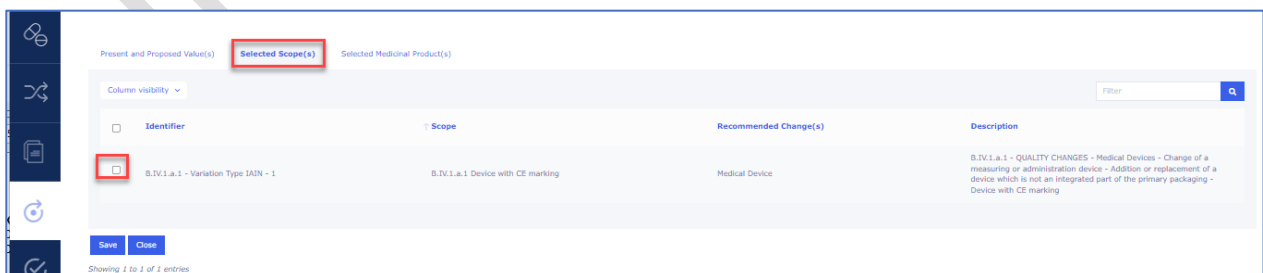
Proposed Change [v] Search [q] **Add Present/Proposed**

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

Figure 58. Selected Scope(s)



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

Column visibility [v] Filter [q]

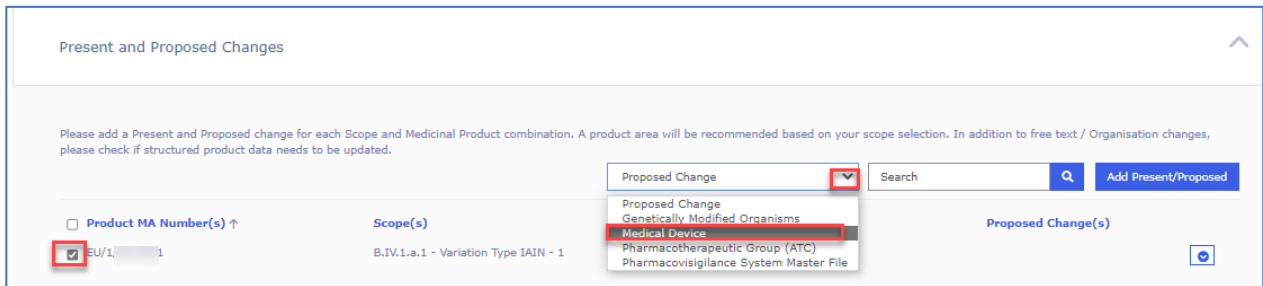
Identifier	Scope	Recommended Change(s)	Description
<input checked="" type="checkbox"/> B.TV.1.a.1 - Variation Type 1A1N - 1	B.TV.1.a.1 Device with CE marking	Medical Device	B.TV.1.a.1 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking

Save Close

Showing 1 to 1 of 1 entries

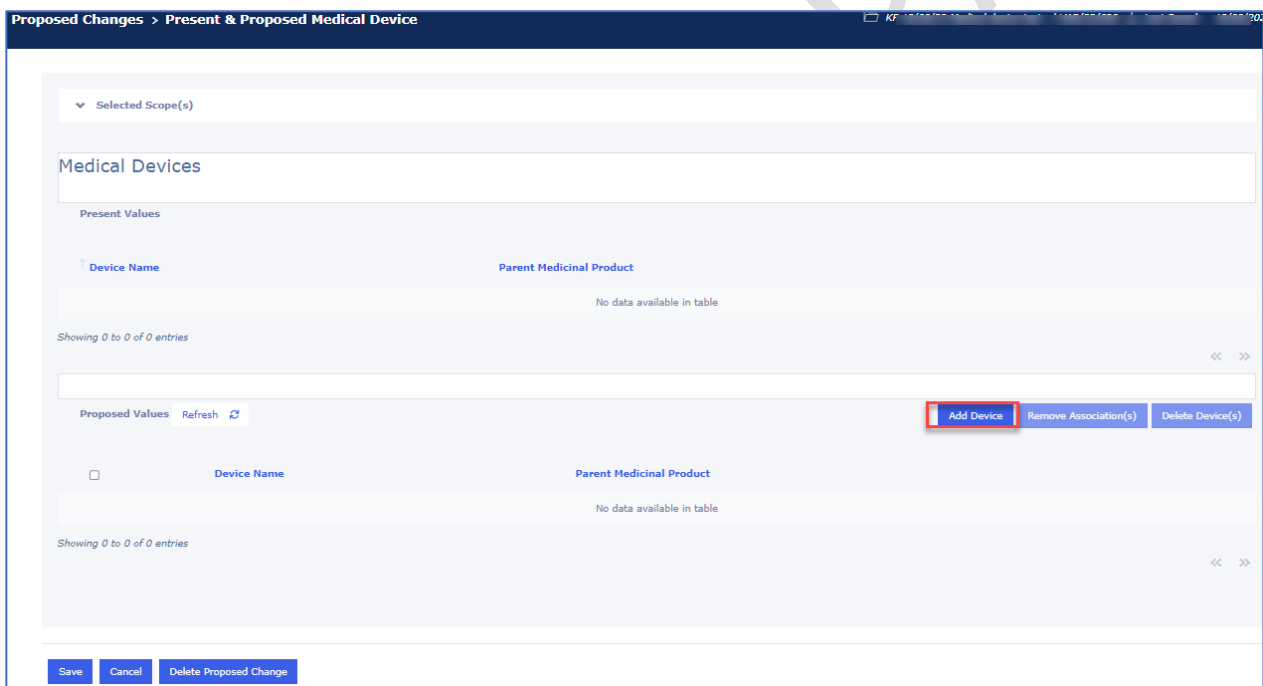
4. When you return to 'Proposed Changes main section, select the relevant product/scope combination by using the tick box and select Medical Device from the dropdown menu. The product must be selected for the dropdown menu to **work**.

Figure 59. Selection of relevant scope/product combination



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

Figure 60. Add Device



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

Figure 61. Medical Device and Companion Diagnostic

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;

Figure 62. Change Selection - Medical Device and Companion Diagnostic

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 proposed change 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

Figure 63. Device(s) Identification and Classification

Device(s) identification and classification

Name of the Device	Type of Combination ⓘ*
Device Quantity	Device Type *
Classification *	Serial number / unique device identifier (UDI) or other indications necessary to delimit precisely the device incorporated, if applicable *
Intended Purpose of the Device *	Brief Description of the Device *

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

Figure 64. Manufacturer of the Device



Manufacturer of the device

Function *

Manufacturer *

Title *

First Name *

Last Name *

Telephone

E-Mail

10. Proceed to fill in the rest of the sections

Figure 65. Upload of Documentation

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

Figure 66. Notified Body

Notified Body (NB)

Notified Body Number *

Name of the Notified Body *

Title *

First Name *

Last Name *

Telephone

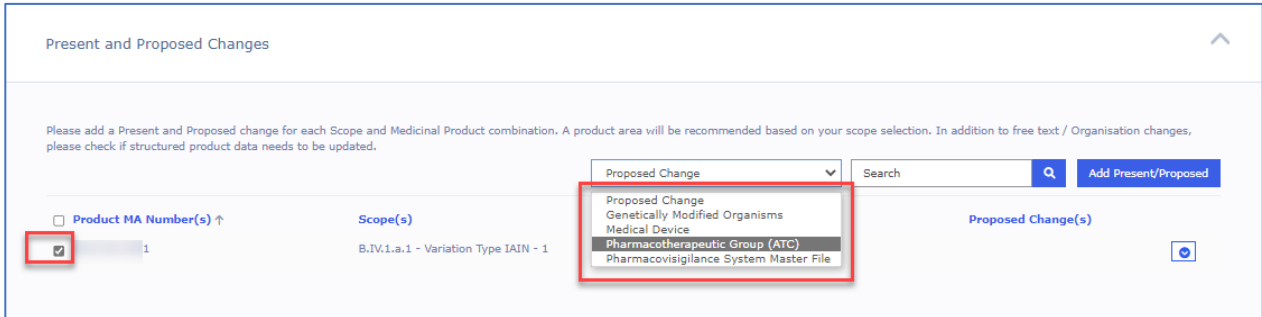
E-Mail

2.5.3.6. ATC Code change

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

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

Figure 67. Present and Proposed Changes



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

1

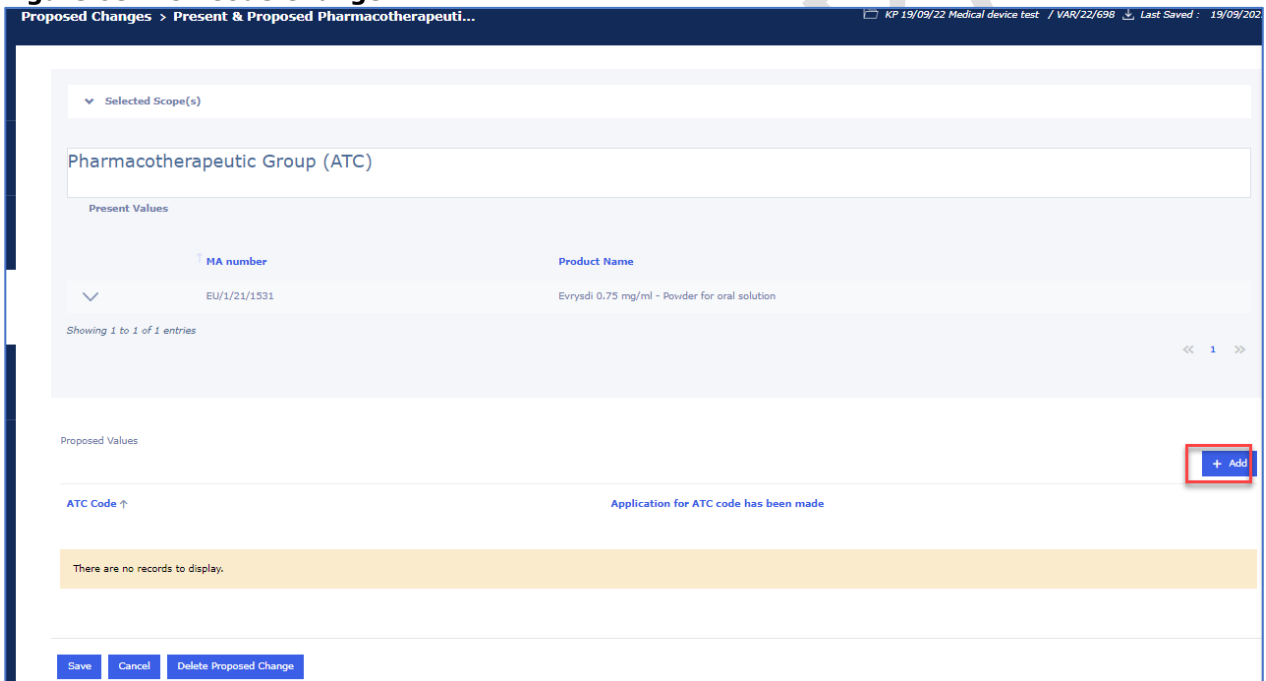
Proposed Change Search **Add Present/Proposed**

Proposed Change(s)

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

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

Figure 68. ACT Code Change



Proposed Changes > Present & Proposed Pharmacotherapeuti...

Selected Scope(s)

Pharmacotherapeutic 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

+ Add

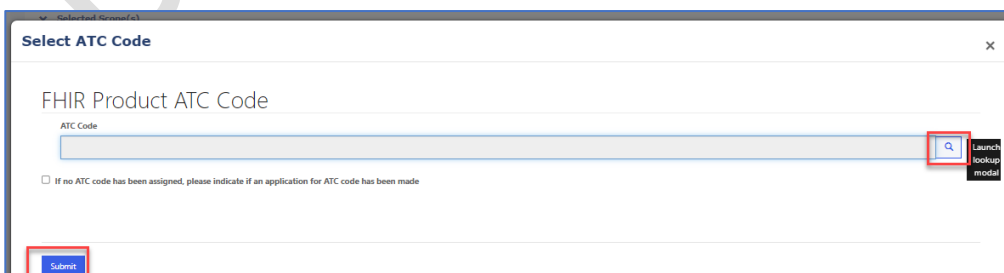
ATC Code ↑ Application for ATC code has been made

There are no records to display.

Save Cancel Delete Proposed Change

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

Figure 69. Selection of ATC Code



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

Submit

Launch lookup modal

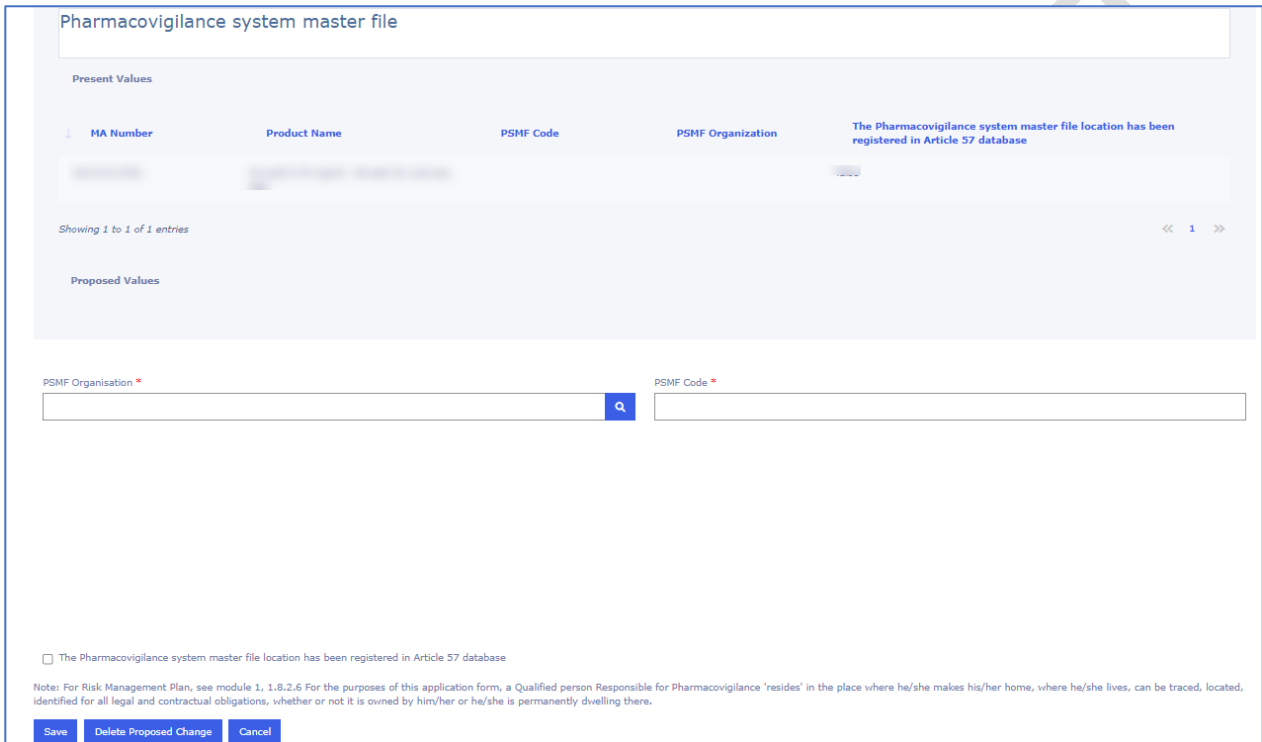
3. Click on the **Submit** button and you will be taken back to the Proposed Changes main page

4. Click on the **Save** button to save your changes in the form

2.5.3.7. Pharmacovigilance System Master File

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

Figure 70. Pharmacovigilance System Master File



Pharmacovigilance system master file

Present Values

HA 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

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

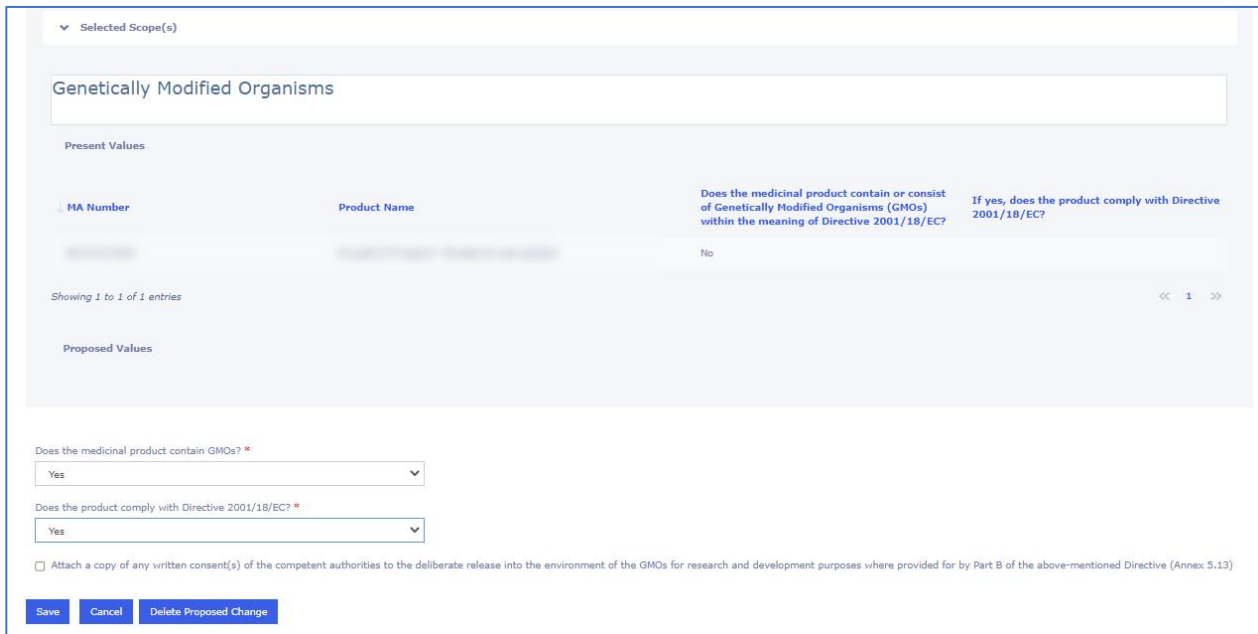
Click on the **Save** button and you will be taken back to the Proposed Changes main page

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

2.5.3.8. Genetically Modified Organisms

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

Figure 71. Genetically Modified Organisms Code



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

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

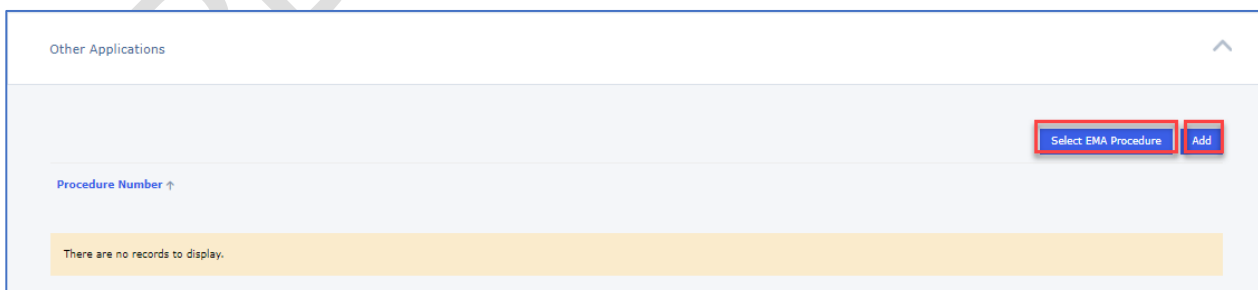
Click on the **Save** button to save your changes in the form

2.5.4. Other applications

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

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

Figure 72. Selection of EMA Procedure



Other Applications

Procedure Number ↑

There are no records to display.

Select EMA Procedure Add

2.6. Additional Information

The additional information section contains the sections 4a, 4b and 4c of the pdf eAF. These sections are only visible in the form depending on the previous selections in the form. Please note that there is

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

Figure 73. Additional Information Section



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


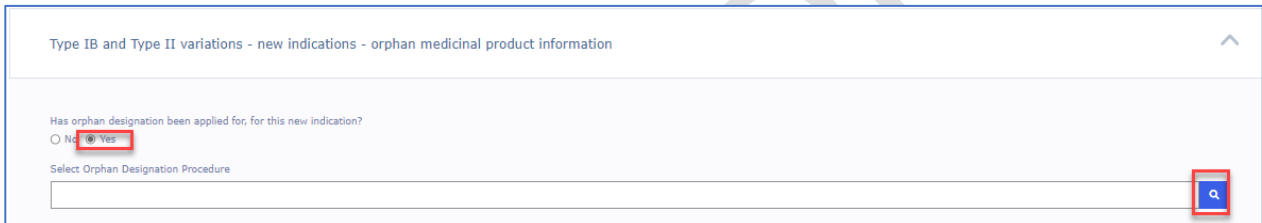
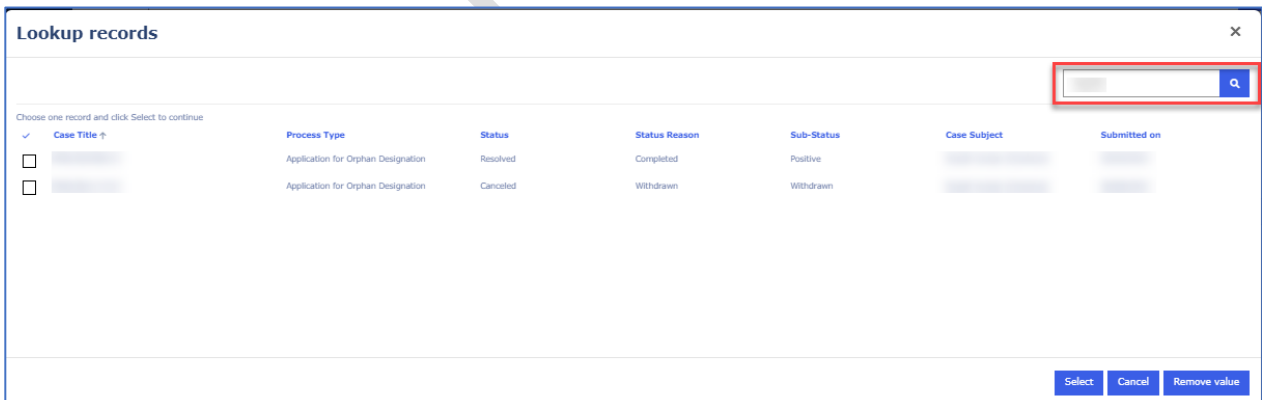
1. To fill in this section select the relevant orphan designation using the magnifying glass 

Figure 74. Orphan Designation Procedure



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

Figure 75. Lookup Records



Case Title	Process Type	Status	Status Reason	Sub-Status	Case Subject	Submitted on
<input type="checkbox"/>	Application for Orphan Designation	Resolved	Completed	Positive		
<input type="checkbox"/>	Application for Orphan Designation	Canceled	Withdrawn	Withdrawn		

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

Figure 76. Selection of 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

Details to be added

2.6.3. Type IB and Type II Variations – Paediatric Requirements

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

Figure 77. Type IB and Type II Variations – Paediatric Requirements

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

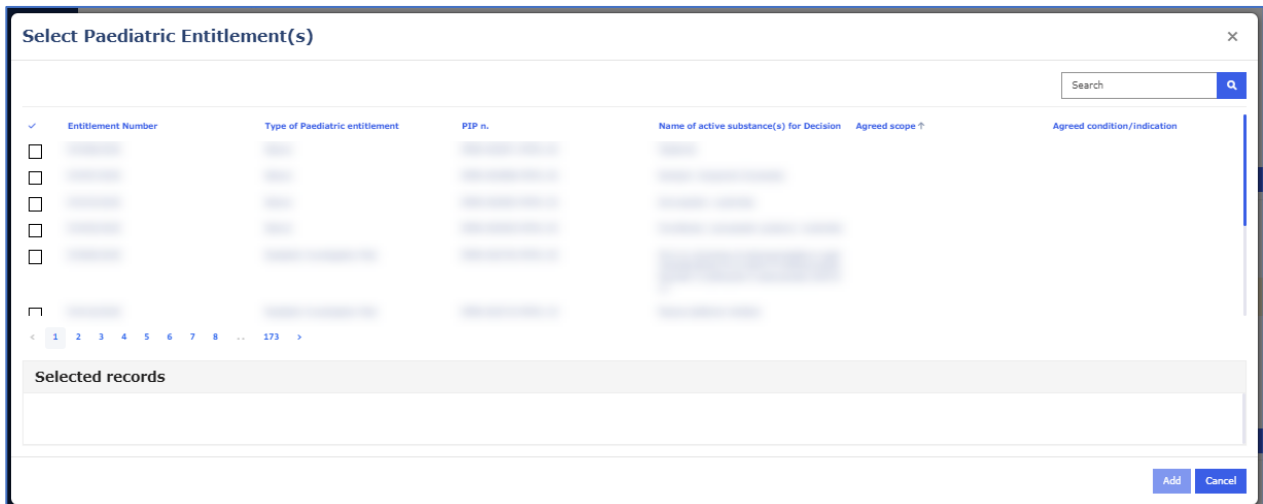
[+ Add](#)

The compliance document reference ↑

There are no records to display.

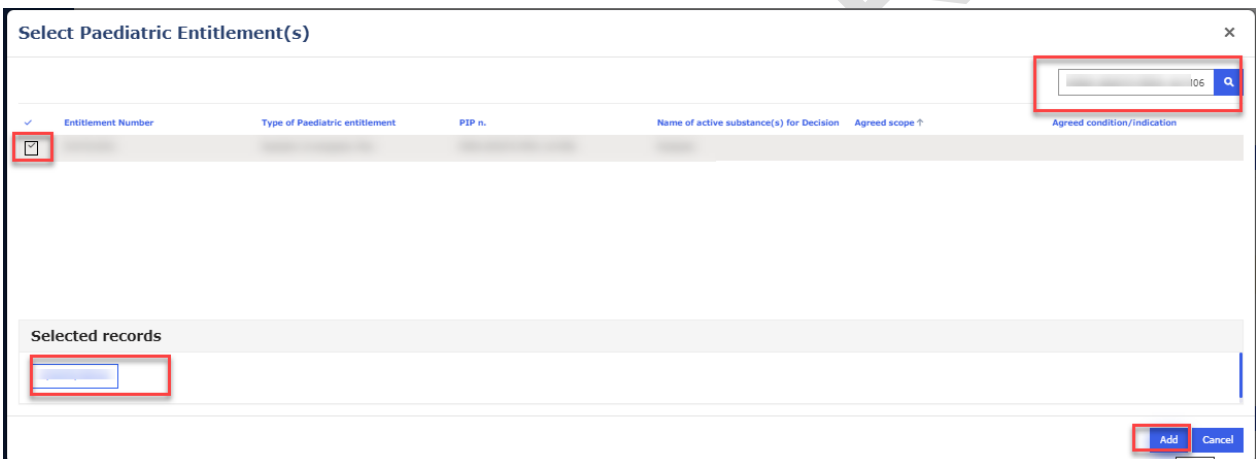
1. Select the Paediatric Entitlement(s) using the search

Figure 78. Selection of Paediatric Entitlement(s)



2. Add the entitlement

Figure 79. Addition of Paediatric Entitlement(s)



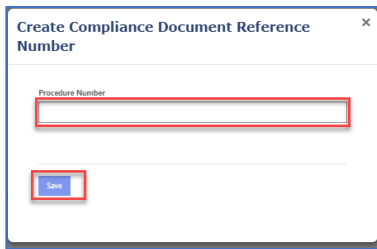
The details are shown in the table and the entitlement can be removed using the arrow on the right

Figure 80. Recap Table of Paediatric Entitlement(s)



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

Figure 81. Creation of Compliance Document Reference Number



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

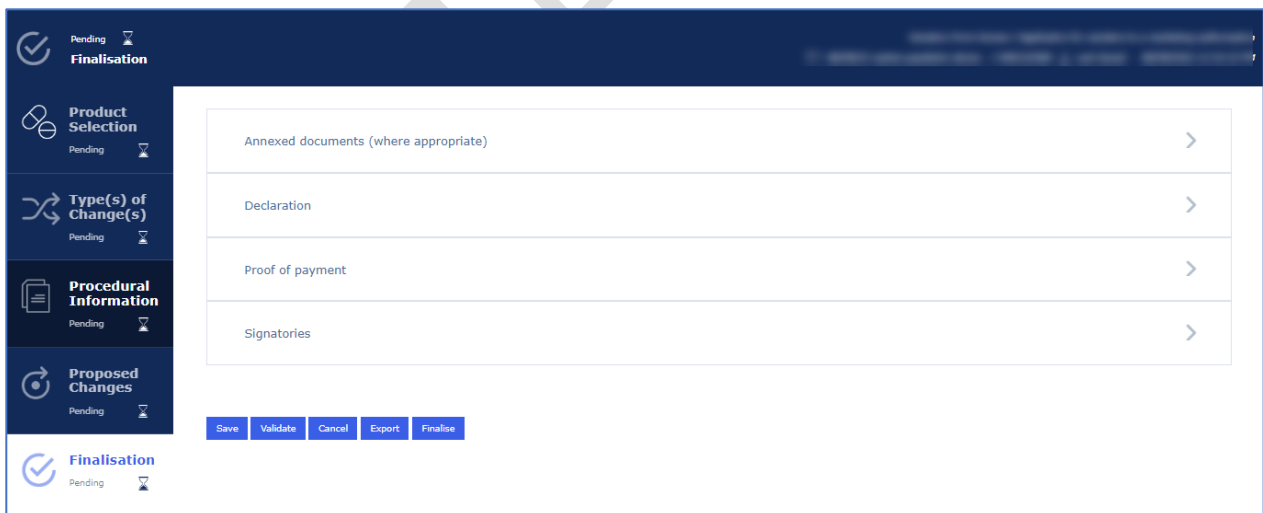
Figure 82. Type II Variations – Extended data exclusivity/market protection



2.7. Finalisation

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

Figure 83. Finalisation Process



2.7.1. Annexed documents (where appropriate)

Figure 84. Annexed Documents

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

Figure 85. 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

NOTE:

NOTE: There is also a known issue affecting Proof of Payment section for worksharing procedures containing CAPs and non-CAPs. Please note that the section is defaulted to 'No' and it is not possible to include information on pre-payments in NCAs. We are currently working on fixes and improvements to the Proof of Payment section. If the NCAs involved in the worksharing procedure require the information on pre-payments for non-CAP products, please provide this on separate annex to the application form or use the interactive pdf eAF. The EMA does not require information on pre-payments for NCAs for EMA led WS procedures.

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

Figure 86. Proof of Payment

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 A msterdam Netherlands		

2.7.4. Signatories

Figure 87 – Signatories

Signatories

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

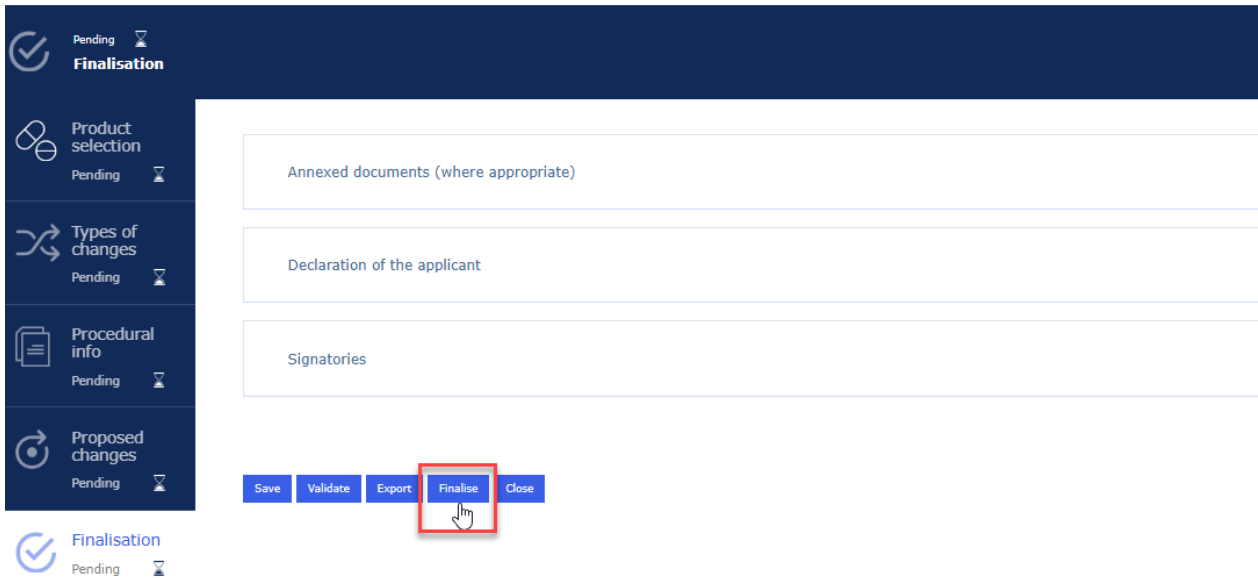
The pdf eAF exported from the web user interface cannot be edited outside the PLM Portal. The forms cannot be signed in the web user interface.

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

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

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

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



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

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

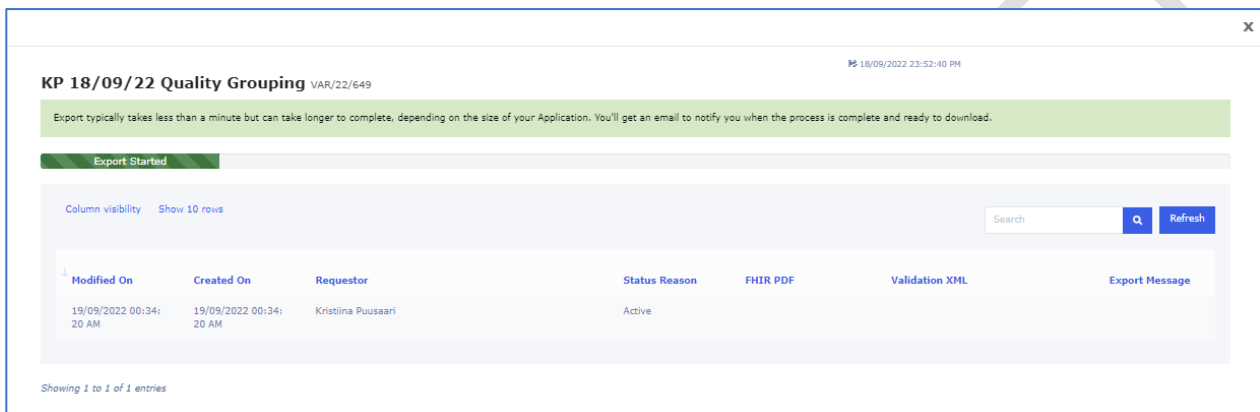
3. Exporting the form content to a PDF

3.1. PDF Export

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

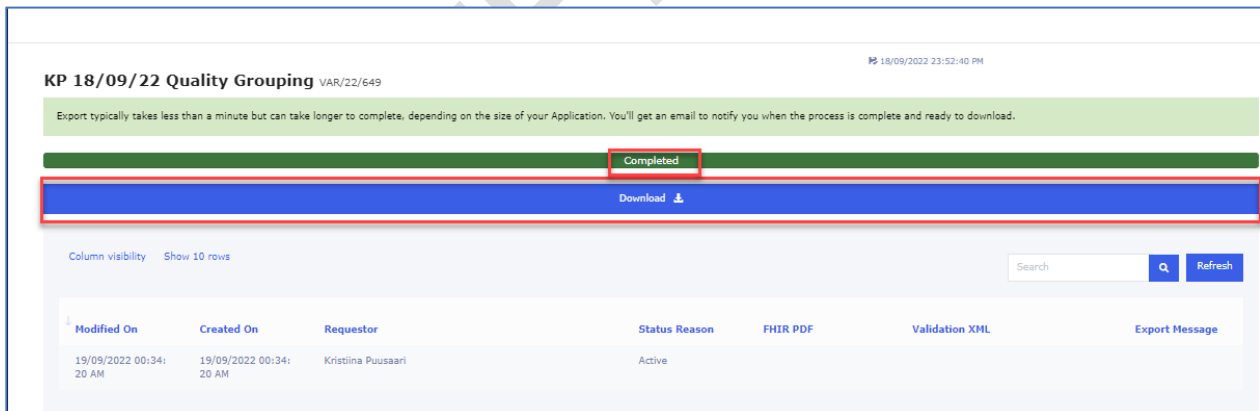
You can see the progress of the export in the moving bar that is constantly updated while the export is being prepared

Figure 88. Preparation of Export



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

Figure 89. Export Completed

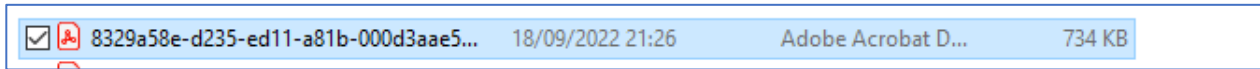


The downloaded forms normally have a name that consists of letters and numbers. You can save this pdf rendition to be reviewed, signed (more details on the use of digital signatures will be provided) and to be included in the dossier. The pdf can be renamed to reflect the eCTD requirements.

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



Figure 90. Exported Form



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

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

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

Figure 91. FHIR xml

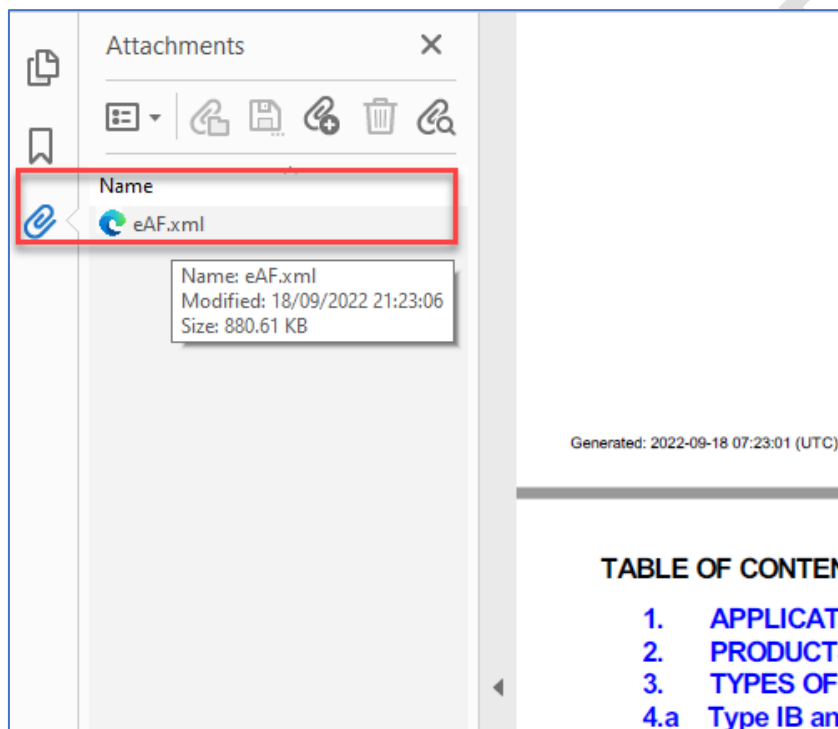


Figure 92. XML file - Document Tree



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

```
<?xml version="1.0" encoding="UTF-8" ?>
<Bundle xmlns="http://hl7.org/fhir">
  <id value="c683504d-41fa-4cf6-9de5-0fb249f77eaa"/>
  <meta>
    <versionId value="V0.1"/>
  </meta>
  <type value="collection"/>
  <entry>
    <resource>
      <Task>
        <id value="8329a58e3aae59e6f8d69a30ce653a8a"/>
        <contained>
          <List>
            <id value="taskProductList"/>
            <status value="current"/>
            <mode value="working"/>
            <entry>
              <item>
                <reference value="MedicinalProductDefinition/3de609f13aaa0711f8d69a30ce653a8a"/>
              </item>
            </entry>
          </List>
        </contained>
        <contained>
          <Task>
            <id value="variation-06abee533aaa0cebf8d69a30ce653a8a"/>
            <identifier>
              <system value="http://ema.europa.eu/fhir/scopeIdentifier"/>
              <value value="C.I.6.a - Variation Type II - 1"/>
            </identifier>
            <partOf>
              <reference value="#"/>
            </partOf>
            <status value="requested"/>
            <intent value="order"/>
            <code>
              <coding>
                <system value="https://spor.ema.europa.eu/v1/lists/100000152091"/>
                <code value="100000152602"/>
                <display value="C.I.6.a Addition of a new therapeutic indication or modification of an approved one"/>
              </coding>
              <text value="100000152602"/>
            </code>
            <input>
              <type>
                <coding>
                  <system value="https://spor.ema.europa.eu/v1/lists/9000000001"/>
                  <code value="9000000004"/>
                  <display value="Not Applicable"/>
                </coding>
              </type>
              <valueBoolean value="false"/>
            </input>
          </Task>
        </contained>
      </Task>
    </resource>
  </entry>
</Bundle>
```

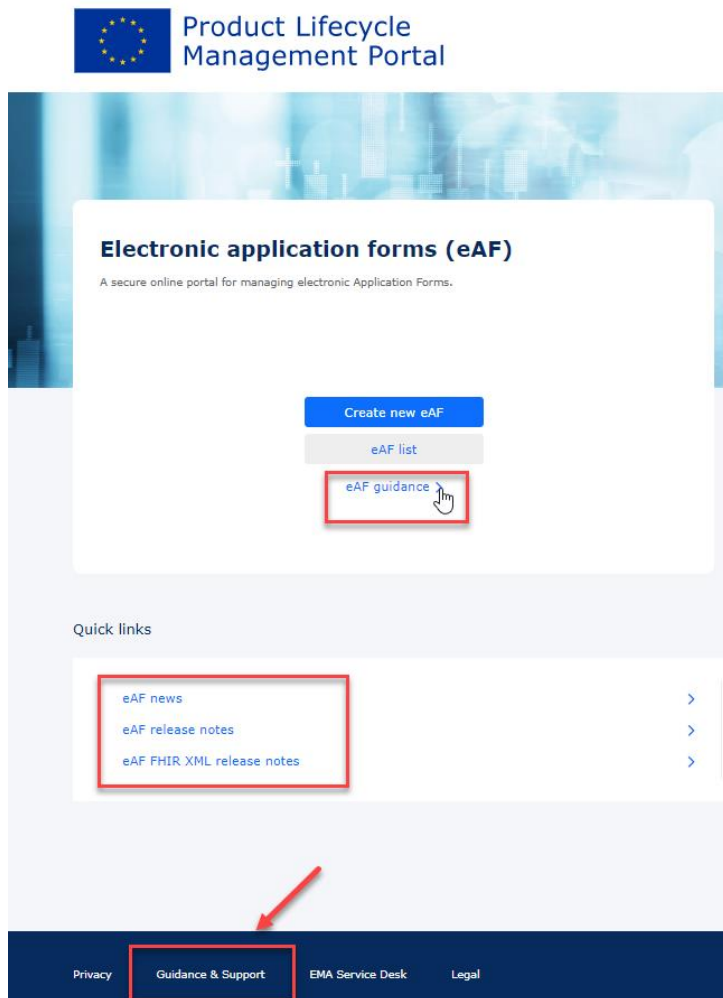
3.2. PDF Requirements

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 PLM Portal eAF Guidance materials

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



4.2. The PLM Forum

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

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

1. [EMA Service Desk](#) for questions on the use of the portal and for reporting faults;

2. [EMA Account Management](#) for access and registration requests;

3. [Ask EMA](#) for general questions not related to a specific submission/procedure;

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



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

4.3. *The Service Desk*

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

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

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

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

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

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

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

Figure 93. Report an Issue with PLM Portal (eAF) Form



Report an issue with PLM portal (eAF)

Request assistance on a PLM Portal – eAF issue.



Create a ticket for the issue you are experiencing.

Before creating a new ticket, please double check the available guidance - the issue you are experiencing may be explained there.

[PLM Portal – Human Variations eAF: Guide to registration](#)

[PLM Portal – Human Variations eAF: Guide to navigation](#)

[PLM Portal – eAF | How to monitor Application Forms Status](#)

[PLM Portal – eAF | How to select the scope of the variation application](#)

[PLM Portal – eAF | How to fill in the "Procedural Information" section](#)

[PLM Portal – eAF | How to fill in the "Additional Information" section](#)

[PLM Portal – eAF | How to fill in the "Finalisation" section](#)

Please provide as much detail as possible (incl. step-by-step narrative and/or screenshot(s) as attachments, if/when applicable). Example: report an issue pertaining the filling of an electronic Application Form: Web-user interface / Data / Access / FHIR XML / PDF export / Regulation / Other

* Indicates required

* Raise this request on behalf of

* Subject

* Description

* Problem area


* Urgency

Add attachments

Figure 94. Request for Information - PLM Portal (eAF) Form

Request for information - PLM portal (eAF)

Request assistance on a PLM Portal – eAF issue



Create a ticket for the issue you are experiencing.

Before creating a new ticket, please double check the available guidance - the issue you are experiencing may be explained there.

[PLM Portal – Human Variations eAF: Guide to registration](#)
[PLM Portal – Human Variations eAF: Guide to navigation](#)
[PLM Portal – eAF | How to monitor Application Forms Status](#)
[PLM Portal – eAF | How to select the scope of the variation application](#)
[PLM Portal – eAF | How to fill in the "Procedural Information" section](#)
[PLM Portal – eAF | How to fill in the "Additional Information" section](#)
[PLM Portal – eAF | How to fill in the "Finalisation" section](#)

Please provide as much detail as possible (incl. step-by-step narrative and/or screenshot(s) as attachments, if/when applicable). Example:
report an issue pertaining the filling of an electronic Application Form:
Web-user interface / Data / Access / FHIR XML / PDF export /
Regulation / Other

***** Indicates required

***Raise this request on behalf of**


i Kristiina Puusaari ✕ ▼

***Subject**

***Description**

***Problem area**

▼

 Add attachments

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

Please see more details on how to report issues from this [presentation slides 22-24](#).

4.4. The PLM Chatbot



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


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

Figure 95. PLM Chatbot

