



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guide to navigation – June 2025 update

Product Lifecycle Management Portal – Human Variations eAF

CAPs and non-CAPs

Version 1.9

UPDATED DRAFT
including non-CAPs

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Acronym key and glossary terms

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

1. Purpose and Context

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

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

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

1.1. Purpose of this guide

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

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

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

1.2. Preliminary requirements

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

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

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

1.3. Supported Browsers

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

2. Navigation through the PLM Portal - eAF

2.1. Creating an application form

2.1.1. How to access the PLM Portal eAF

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

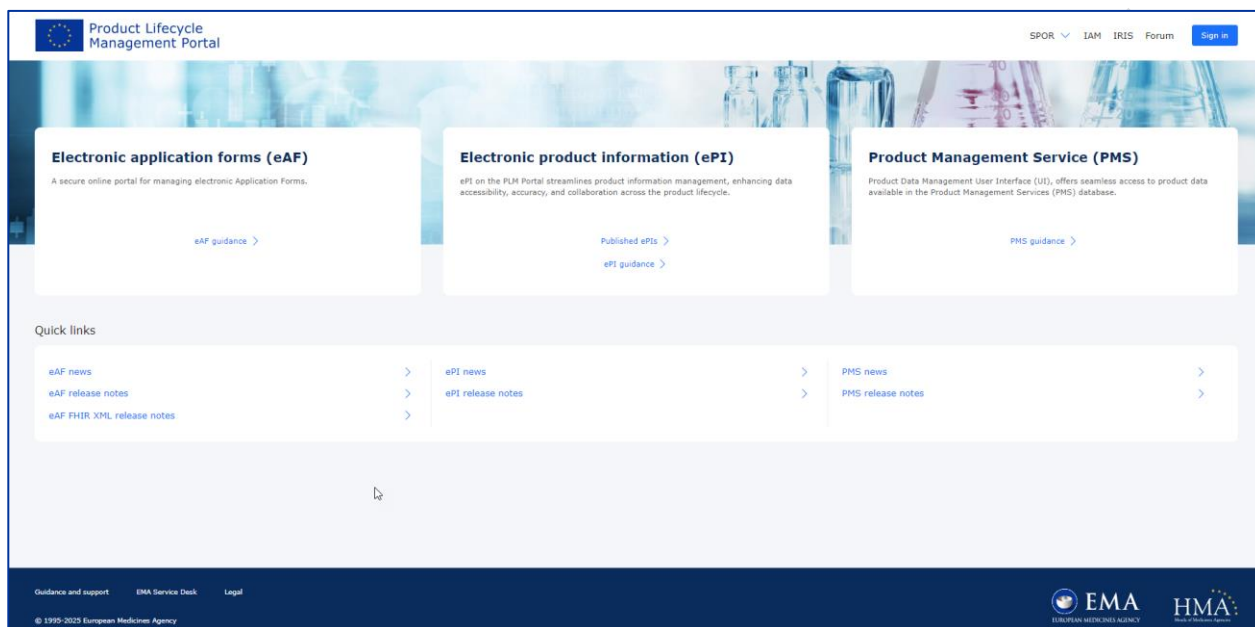


Figure 1 - Sign-in

2.1.2. How to create a new electronic Application Form

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

1. Sign into the PLM Portal – eAF

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

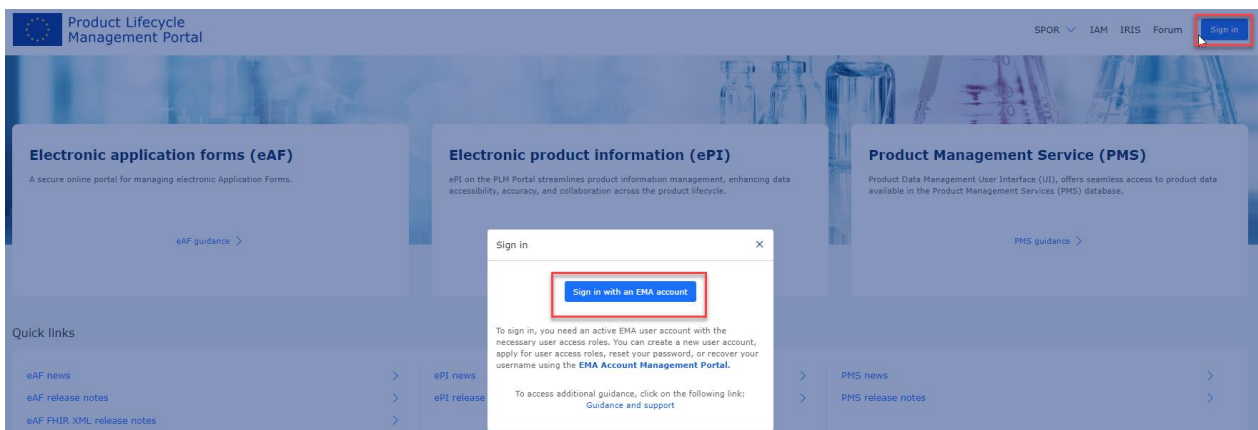


Figure 2 - Sign-in button

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

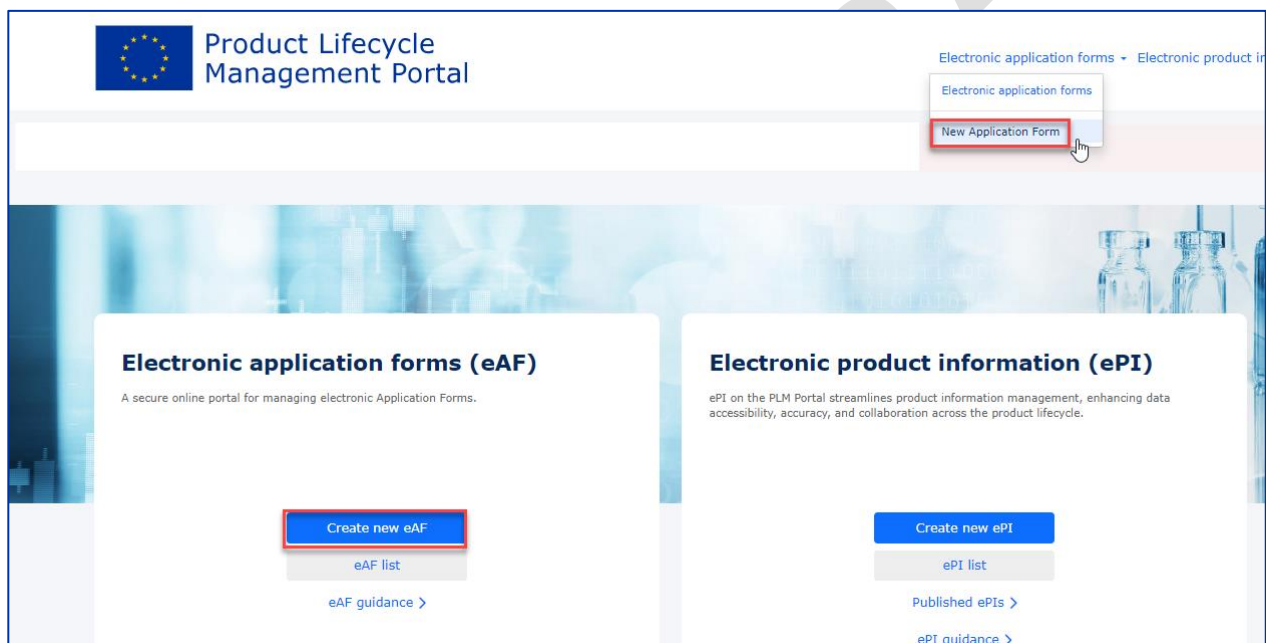


Figure 3 - New Application Form

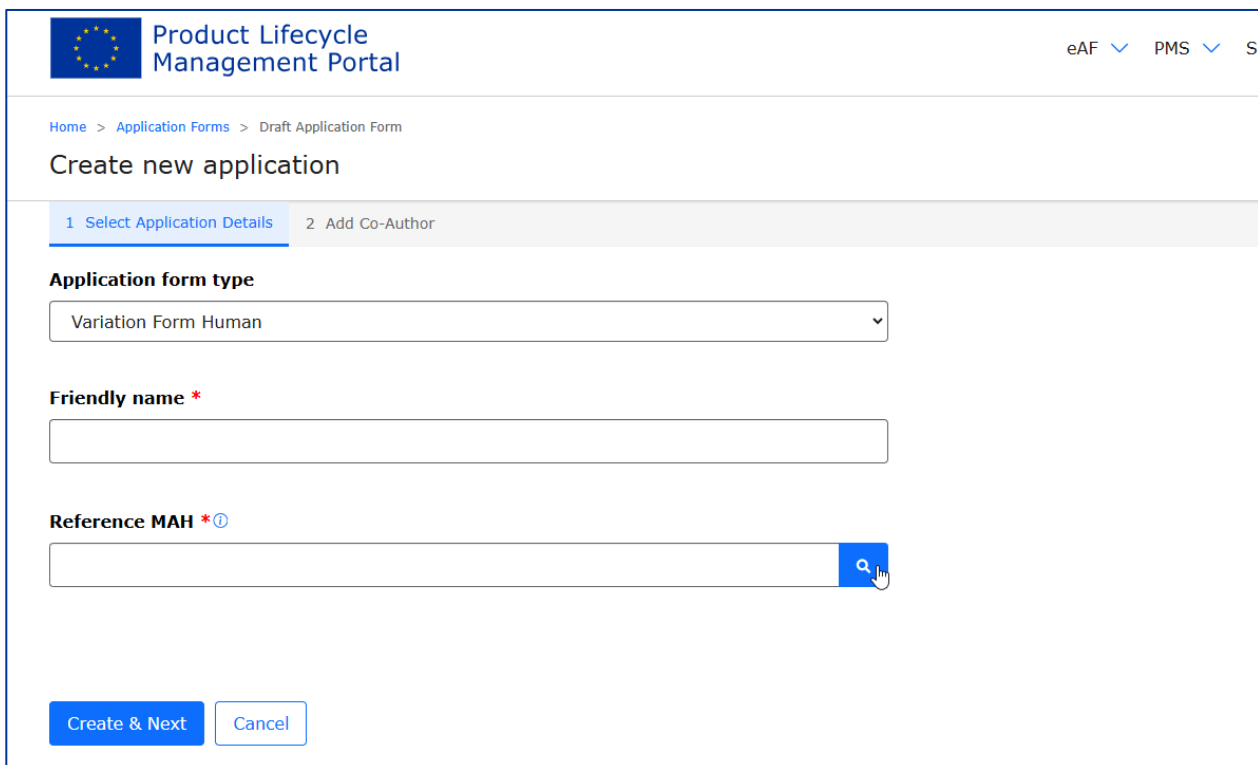
- Click on [Create new eAF/New Application Form](#)

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.



Product Lifecycle Management Portal

eAF ▼ PMS ▼ SF

Home > Application Forms > Draft Application Form

Create new application

1 Select Application Details 2 Add Co-Author

Application form type

Variation Form Human ▼

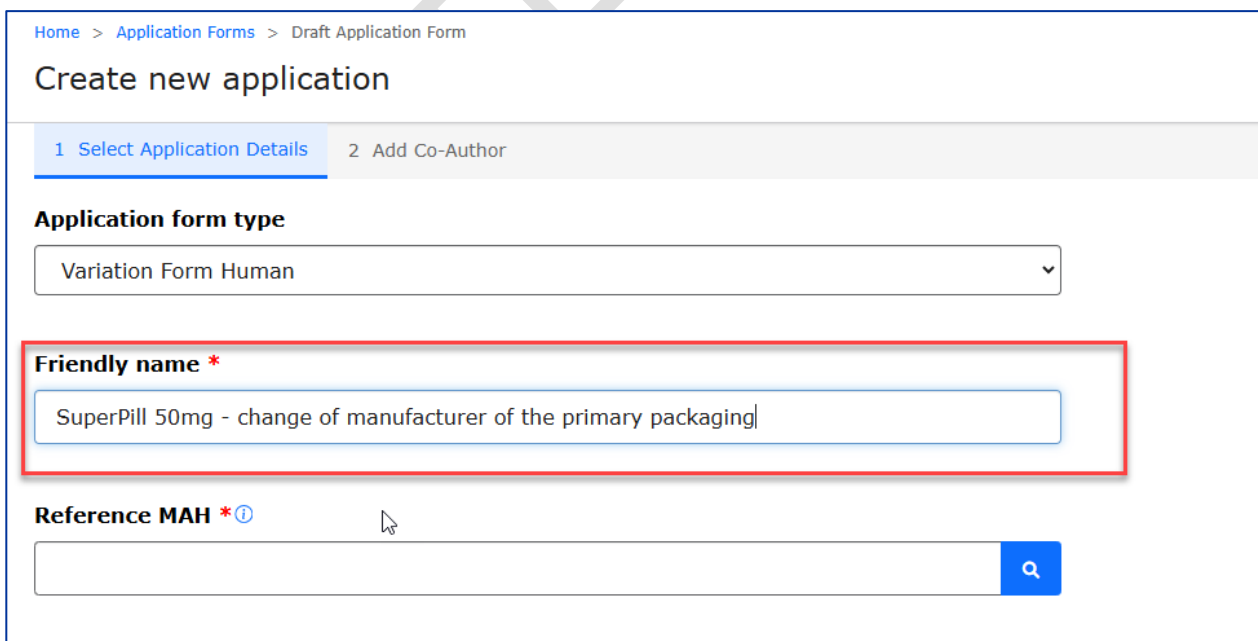
Friendly name *

Reference MAH * ⓘ

Create & Next Cancel

Figure 4 - Application Form Type

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



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 *

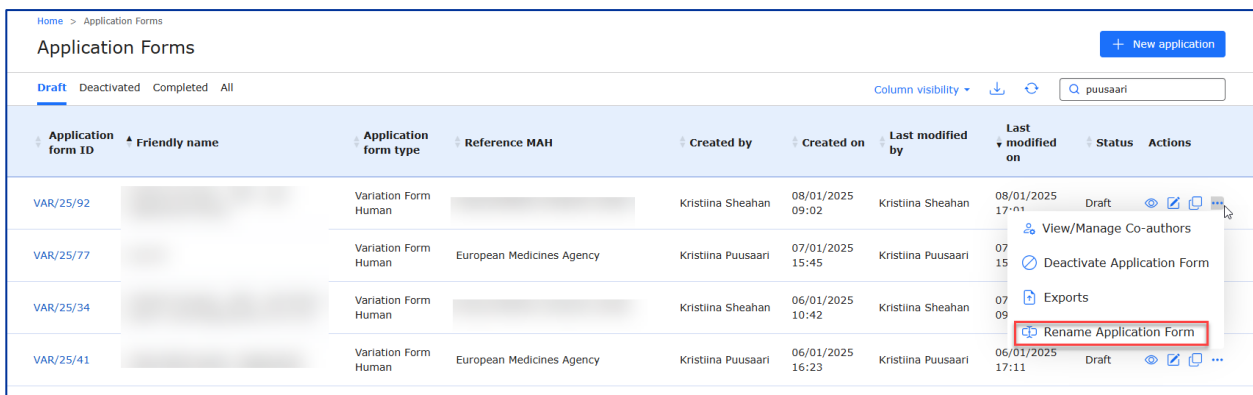
SuperPill 50mg - change of manufacturer of the primary packaging

Reference MAH * ⓘ

Figure 5 - Application Details


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

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



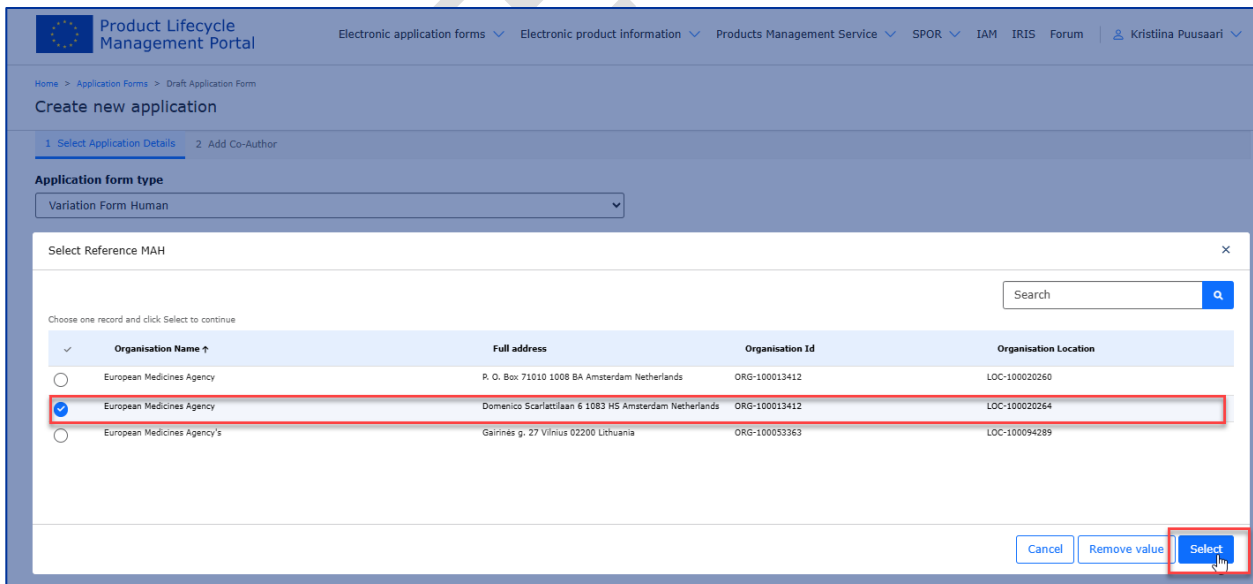
Application form ID	Friendly name	Application form type	Reference MAH	Created by	Created on	Last modified by	Last modified on	Status	Actions
VAR/25/92		Variation Form Human		Kristiina Sheahan	08/01/2025 09:02	Kristiina Sheahan	08/01/2025 17:01	Draft	View/Manage Co-authors, Deactivate Application Form,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

Figure 6 - Re-name 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 attributes, such as the LOC or ORG-id, the company name or address.

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

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



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

Choose one record and click Select to continue

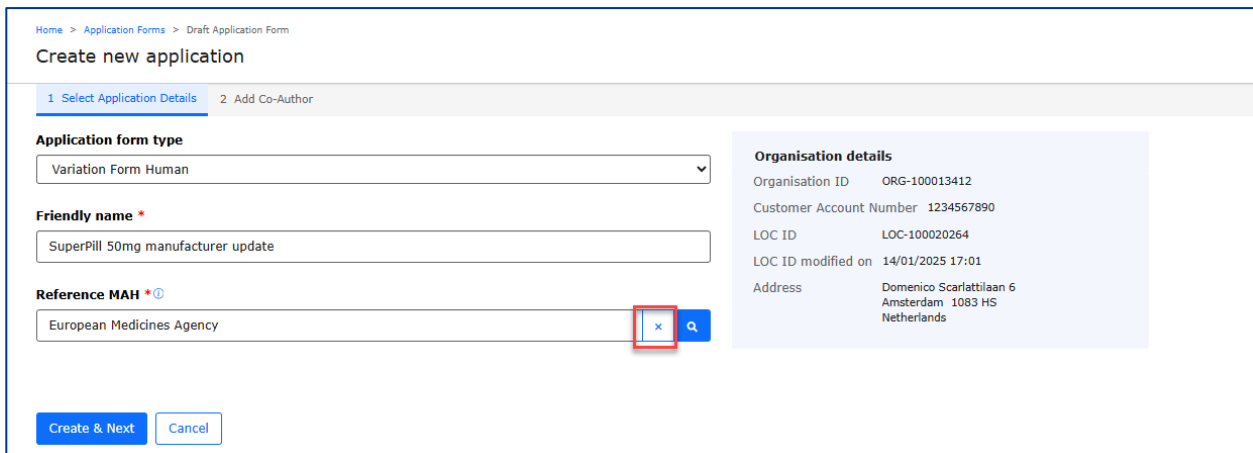
Organisation Name	Full address	Organisation Id	Organisation Location
<input type="radio"/> European Medicines Agency	P. O. Box 71010 1008 BA Amsterdam Netherlands	ORG-100013412	LOC-100020260
<input checked="" type="radio"/> European Medicines Agency	Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands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

Cancel Remove value **Select**

Figure 7 - Reference MAH

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

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



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

Figure 8 - Create & Next Button

- 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.

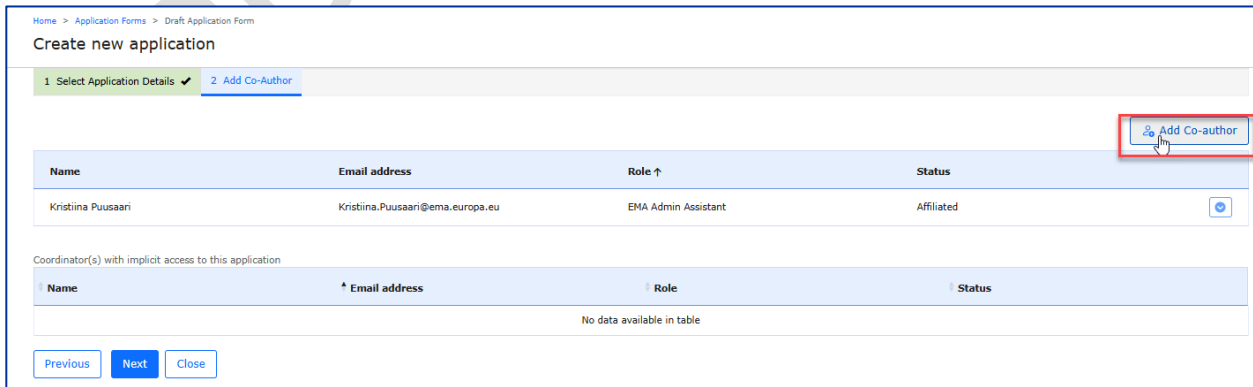
In the 2. Add Co-Author screen, you may:

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.



Home > Application Forms > Draft Application Form

Create new application

1 Select Application Details 2 Add Co-Author

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

Figure 9 - Add Co-Author

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

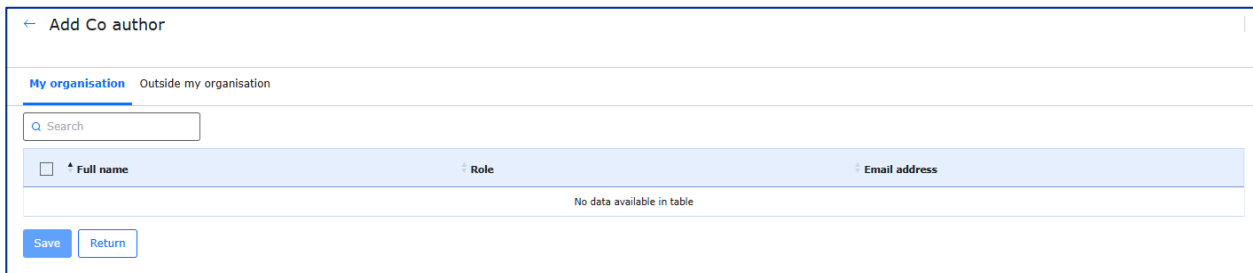


Figure 10 - My Organisation Affiliate(s)' Tab

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

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

Please note that in one go you can add:

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

Click on the **Save** button

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

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

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

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

←

Add Co author

My organisation

Outside my organisation

Q

Q

Info

All users, including co-authors, must be registered with EMAs Identity and Access Management system (IAM) and assigned a role belonging to an organisation. Applicant Managers and Applicant Coordinators can invite co-authors from other organisations to co-edit their applications using the invited users email address. Users from other organisations will be granted access to the application form as soon as their role request to the organisation in question has been granted in IAM. You have an option to send a notification to inform the invited co-author about the invitation so that any previously unaffiliated users can request affiliation in IAM. Different roles with different levels of access are available in IAM:

- Adding **Applicant Contributors** will enable sharing this application with them, however, restricts features like Finalisation, Adding Co-Authors, Export for viewing medicinal product information not contained in the application
- Adding **Applicant Managers** will enable sharing this application with these users, enables all functions, and also shares all medicinal products of the organisations the users are affiliated to (**including commercially confidential information**)
- Adding **Applicant Coordinators** will automatically share all applications and medicinal products (**including commercially confidential information**) with these users. Applicant Coordinators do not need to be added as co-authors explicitly

Full name

Email address

Kristina Sheahan

Save

Cancel

Figure 11 - Add Co-author

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

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

Home > Application Forms

Application Forms

New application

Draft

Deactivated

Completed

All

Column visibility

Download

Refresh

Search puusaari

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

Figure 12 - View/Manage Co-authors

Home > Application Forms > View/Manage Co-Author

View/manage co-author

[Add Co-authors](#)

Name	Email address	Role ↑	Status
Kristiina 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](#)

Figure 13 - Add Co-author

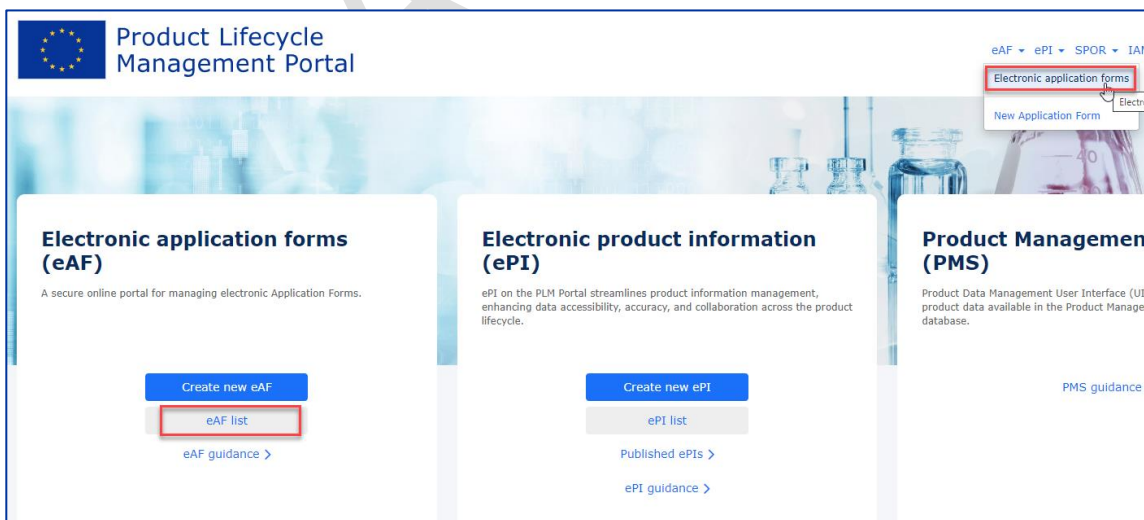
2.1.3. How to access previously created/edited electronic Application Form(s)

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

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

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

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

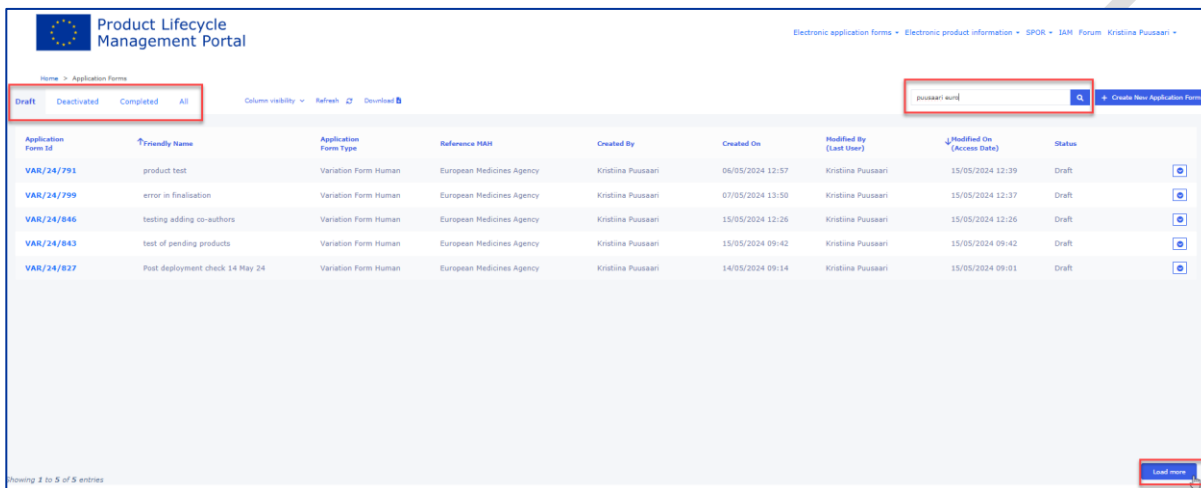


The image shows the Product Lifecycle Management Portal home page. At the top, there is a navigation bar with links for eAF, ePI, SPOR, and IAN. Below this, there are three main sections: Electronic application forms (eAF), Electronic product information (ePI), and Product Management (PMS). Each section has a 'Create new' button and a list of links. In the eAF section, the 'eAF list' link is highlighted with a red box. In the ePI section, the 'ePI list' link is highlighted with a red box. In the PMS section, the 'PMS guidance' link is highlighted with a red box.

Figure 14 – eAF List

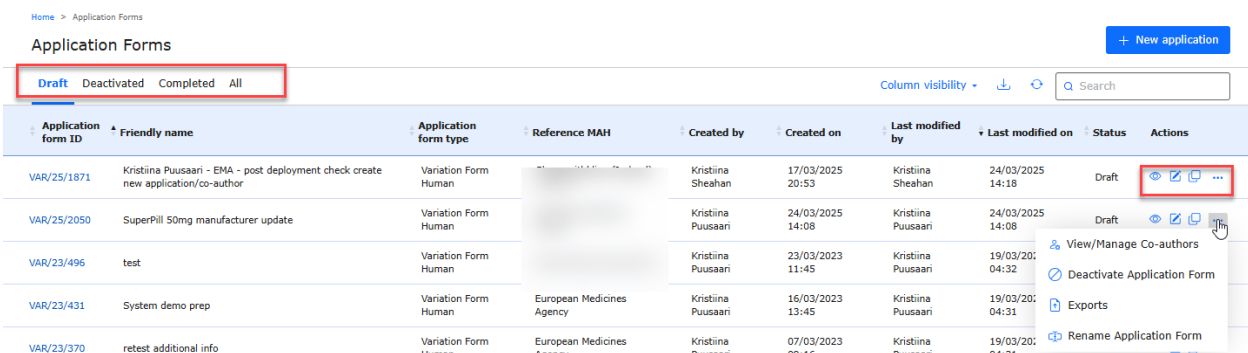
Depending on your access role(s)/permissions, you will see a list of Application Forms available for you:

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



Application Form ID	Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	Modified On (Access Date)	Status
VAR/24/791	product test	Variation Form Human	European Medicines Agency	Kristina Puusaari	06/05/2024 12:57	Kristina Puusaari	15/05/2024 12:39	Draft
VAR/24/799	error in finalisation	Variation Form Human	European Medicines Agency	Kristina Puusaari	07/05/2024 13:50	Kristina Puusaari	15/05/2024 12:37	Draft
VAR/24/846	testing adding co-authors	Variation Form Human	European Medicines Agency	Kristina Puusaari	15/05/2024 12:26	Kristina Puusaari	15/05/2024 12:26	Draft
VAR/24/843	test of pending products	Variation Form Human	European Medicines Agency	Kristina Puusaari	15/05/2024 09:42	Kristina Puusaari	15/05/2024 09:42	Draft
VAR/24/827	Post deployment check 14 May 24	Variation Form Human	European Medicines Agency	Kristina Puusaari	14/05/2024 09:14	Kristina Puusaari	15/05/2024 09:01	Draft

Figure 15 - Application Forms





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	European Medicines Agency	Kristina Sheahan	17/03/2025 20:53	Kristina Sheahan	24/03/2025 14:18	Draft	View/Manage Co-authors, Deactivate Application Form, Exports, Rename Application Form
VAR/25/2050	SuperPill 50mg manufacturer update	Variation Form Human	European Medicines Agency	Kristina Puusaari	24/03/2025 14:08	Kristina Puusaari	24/03/2025 14:08	Draft	View/Manage Co-authors, Deactivate Application Form, Exports, Rename Application Form
VAR/23/496	test	Variation Form Human	European Medicines Agency	Kristina Puusaari	23/03/2023 11:45	Kristina Puusaari	19/03/2023 04:32	Draft	View/Manage Co-authors, Deactivate Application Form, Exports, Rename Application Form
VAR/23/431	System demo prep	Variation Form Human	European Medicines Agency	Kristina Puusaari	16/03/2023 13:45	Kristina Puusaari	19/03/2023 04:31	Draft	View/Manage Co-authors, Deactivate Application Form, Exports, Rename Application Form
VAR/23/370	retest additional info	Variation Form Human	European Medicines Agency	Kristina Puusaari	07/03/2023 09:16	Kristina Puusaari	19/03/2023 04:31	Draft	View/Manage Co-authors, Deactivate Application Form, Exports, Rename Application Form

Figure 16 - List of Application Forms

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


In all four tabs, you may use:

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

- the [Create New Application Form](#) button to initiate a new Application Form.

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

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

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

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

Table 1 - Application Form operations

User	Industry user(s)			NCA user(s)
Role name	(UAT) eAF Applicant	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	(UAT) eAF Competent Authority User
Application Form Status/tab	Contributor			
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 yet developed			

Description of the different operations:

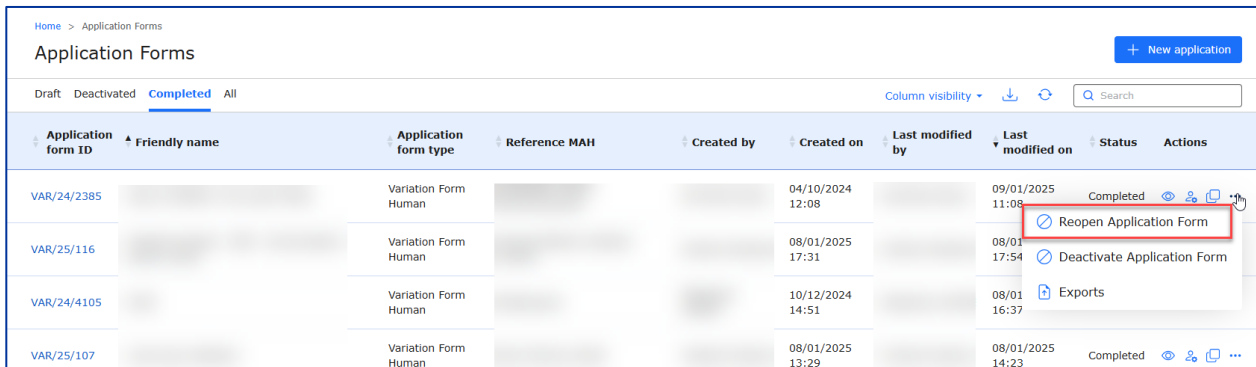
- *Exports* – export generates a [PDF](#) eAF document which contains an FHIR XML attachment,
- *View Co-authors* (available in the 'Deactivated and Completed tabs) – provides a (read-only) list of all previously added co-authors onto a given Application Form;
- *View/Manage Co-authors* (available in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

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

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

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

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



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	Reopen Application Form, 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	

Figure 17 - Reopen Application Form

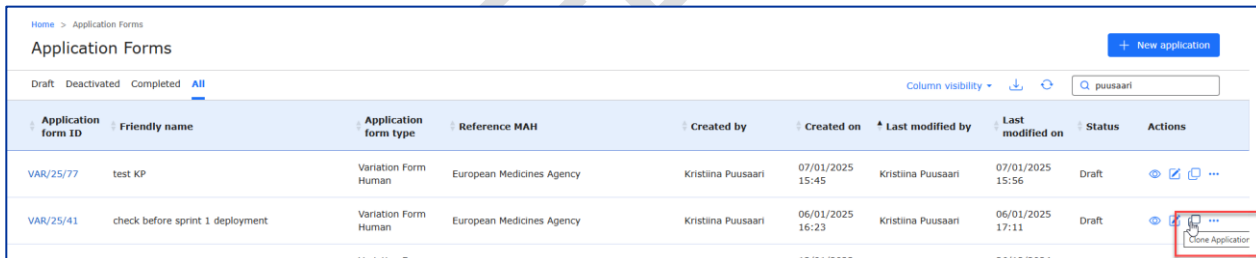
Upon clicking this option, the form in question moves back to the 'Draft' tab where the editing can be continued.

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

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

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

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



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	Clone Application
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	
		Variation Form			12/01/2023		26/12/2024		

Figure 18 - Clone Application

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

This feature caters to two different scenarios:

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

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

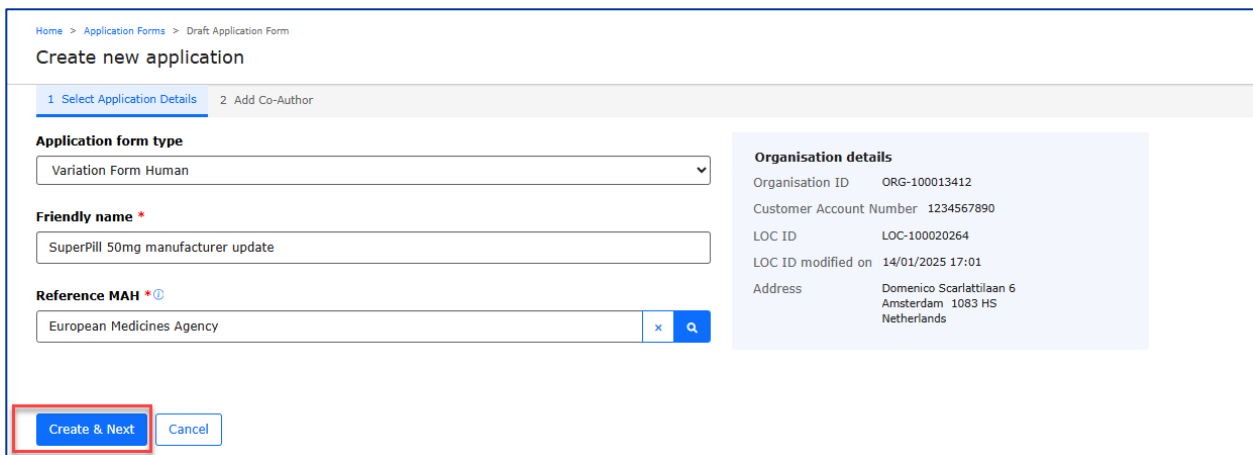


Figure 19 - Create & Next

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

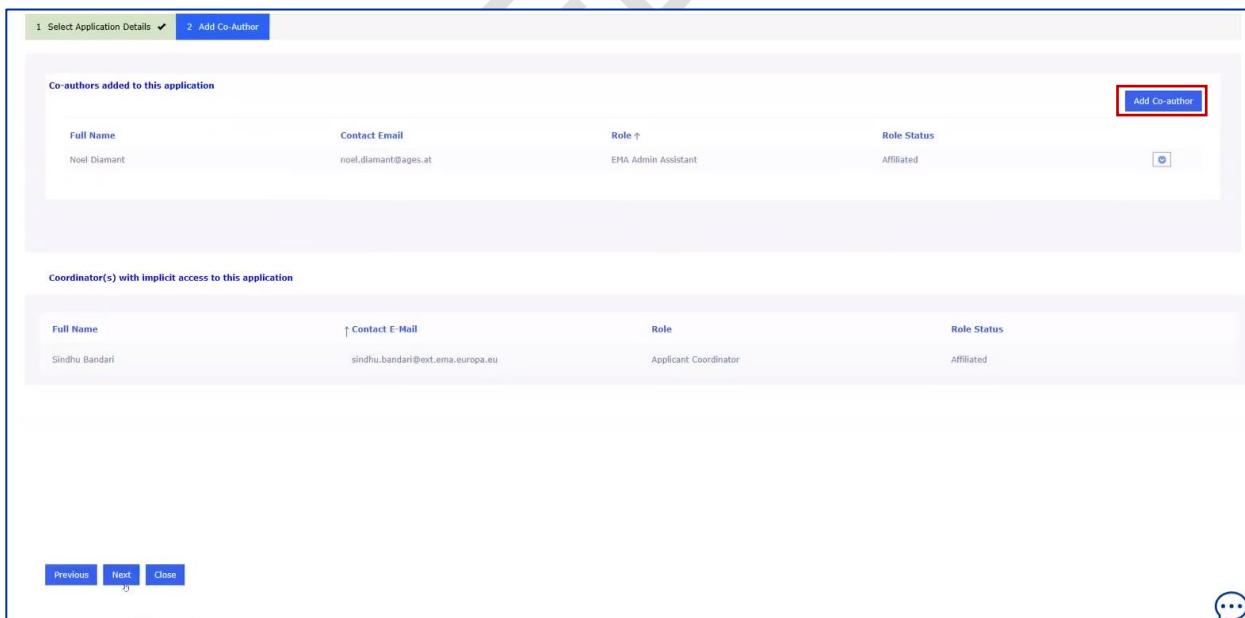
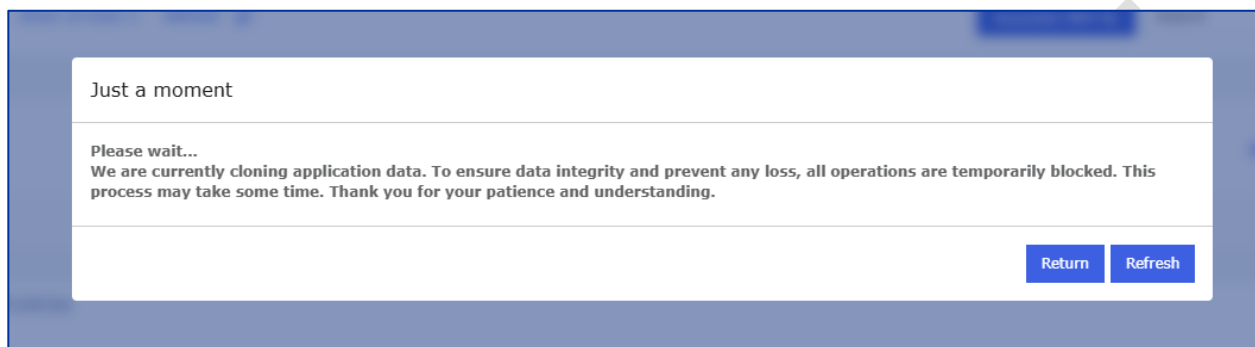


Figure 20 - Add Co-Author

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

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

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

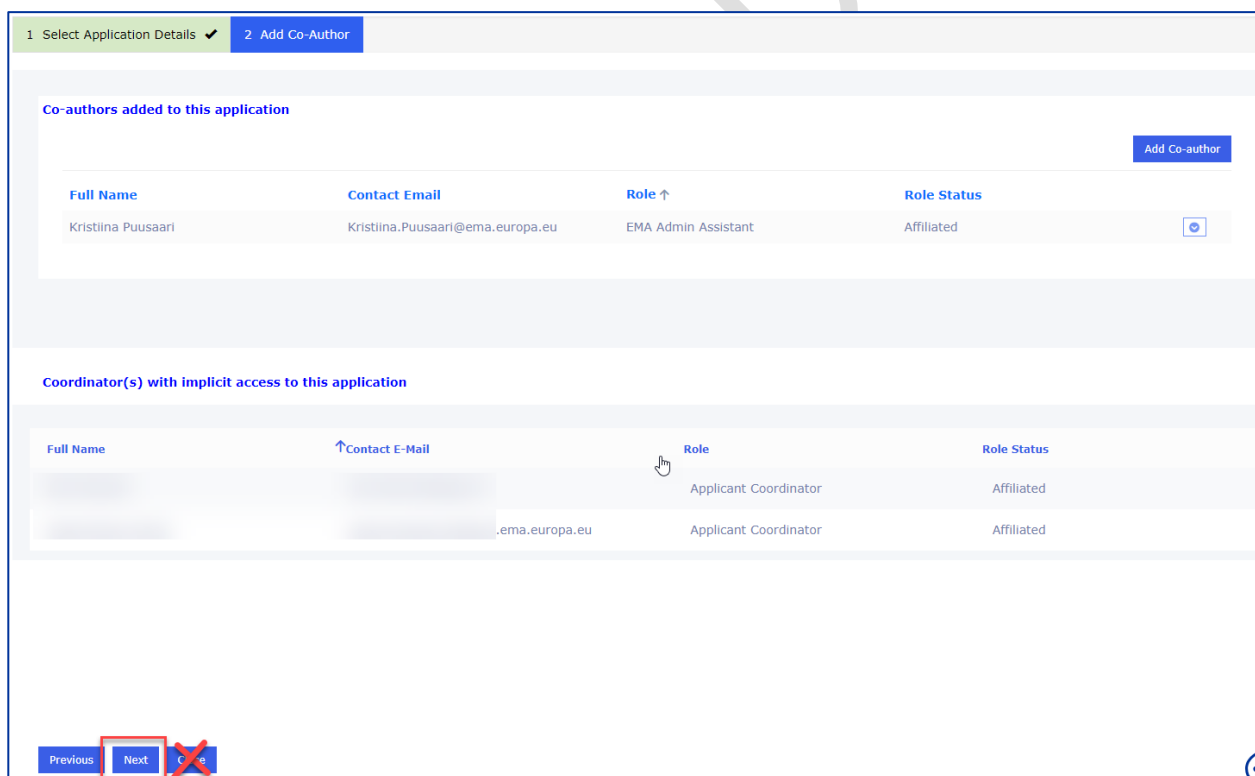


Just a moment

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

Figure 21 - Ongoing Cloning Application Data



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

Previous Next Close

Figure 22 - Cloning Application "Next"

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@ema.europa.eu	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

Figure 23 - Completed Cloning Application

The selected scope is cloned

[Home](#) > [Electronic application forms list](#)
Kristiina Puusaari - EMA - sprint test after ...
Application form ID: VAR/25/3275 | Type: Variation Form Human | Version: 1.2.0.4 | Last saved: 19 May 2025, 09:00

Save
Validate
Exports
Refresh
Close

- Product selection ✓
- Types of changes** ✓
- Procedural info ✓
- Proposed changes ✓
- Finalisation ✗

Types of changes
Variations included for this application

+ Select scope

Scope	Selected	Description	Action
<div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"> <div style="border-bottom: 1px solid #007bff; width: 10px; height: 10px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid #007bff; width: 10px; height: 10px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid #007bff; width: 10px; height: 10px; margin-bottom: 2px;"></div> </div> <div> <div style="background-color: #007bff; color: white; padding: 2px 5px;">A.6</div> <div style="background-color: #007bff; color: white; padding: 2px 5px;">Change in ATC Code / ATC Vet Code</div> </div> </div>	1	A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Vet Code	<div style="background-color: #007bff; color: white; padding: 2px 5px;">Clone Scope</div>

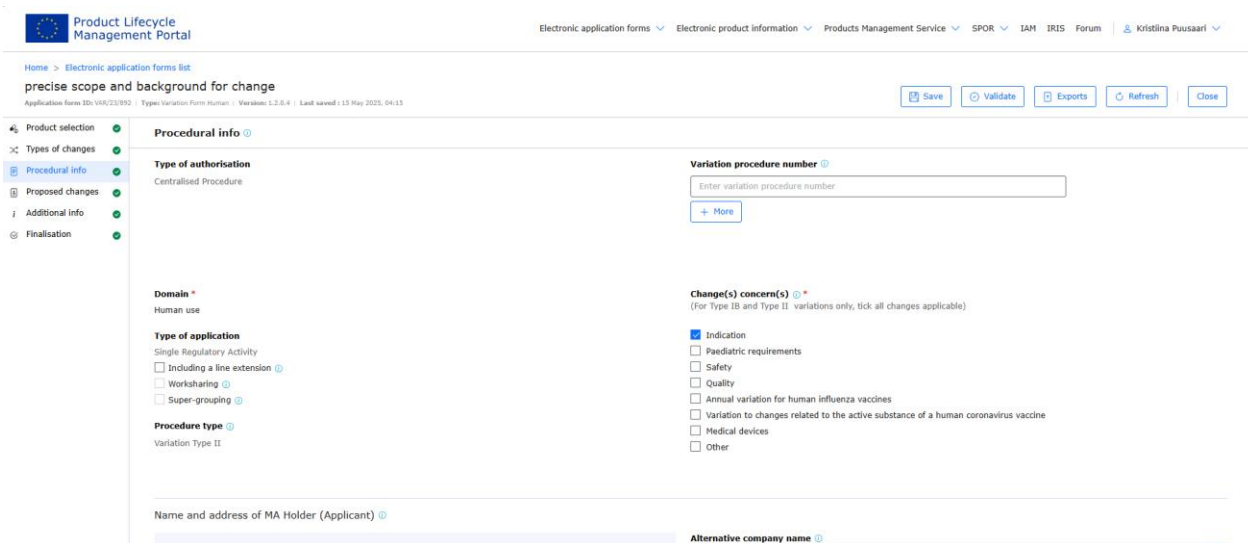
Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5	Action
<div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"> <div style="border-bottom: 1px solid #007bff; width: 10px; height: 10px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid #007bff; width: 10px; height: 10px; margin-bottom: 2px;"></div> <div style="border-bottom: 1px solid #007bff; width: 10px; height: 10px; margin-bottom: 2px;"></div> </div> <div> <div style="background-color: #007bff; color: white; padding: 2px 5px;">A.6</div> <div style="background-color: #007bff; color: white; padding: 2px 5px;">Variation Type IB - 1</div> </div> </div>	Variation Type IB			N/A	<div style="background-color: #007bff; color: white; padding: 2px 5px;">Clone Scope</div>

Figure 24 - Cloned Selected Scope

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Procedural information will also all be cloned



Product Lifecycle Management Portal

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

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precise scope and background for change

Application forms ID: VARI/23/952 | Type: Variation Form Human | Version: 1.2.0.4 | Last saved: 13 May 2025, 04:13

Save | Validate | Exports | Refresh | Close

Product selection | Types of changes | **Procedural info** | Proposed changes | Additional info | Finalisation

Procedural info

Type of authorisation
Centralised Procedure

Variation procedure number
Enter variation procedure number
+ More

Domain *
Human use

Type of application
Single Regulatory Activity
☐ Including a line extension
☐ Worksharing
☐ Super-grouping

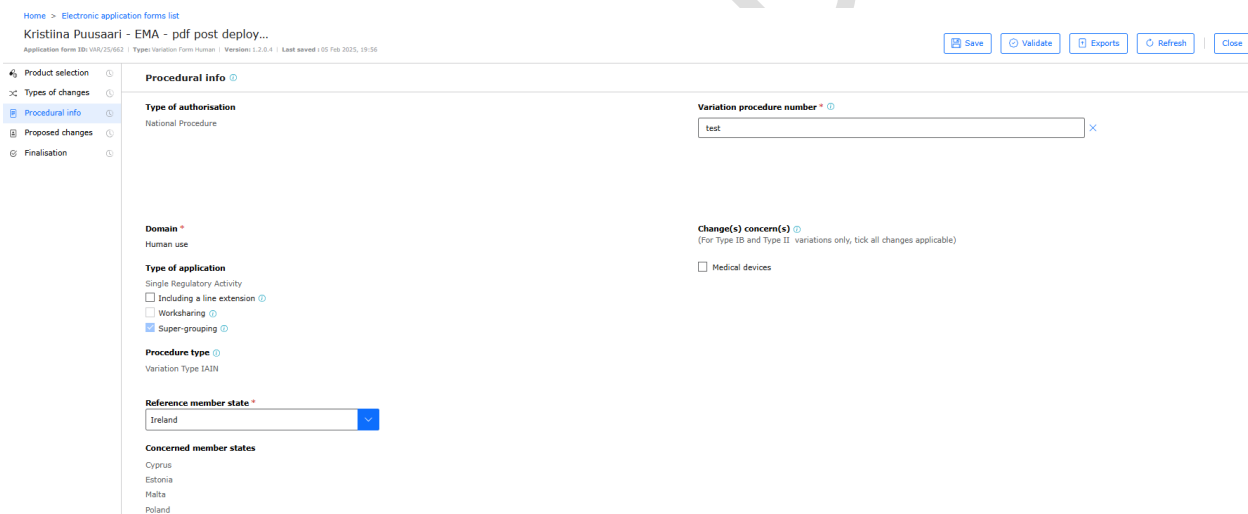
Procedure type
Variation Type II

Change(s) concern(s) *
(For Type IB and Type II variations only, tick all changes applicable)
☒ Indication
☐ Paediatric requirements
☐ Safety
☐ Quality
☐ Annual variation for human influenza vaccines
☐ Variation to changes related to the active substance of a human coronavirus vaccine
☐ Medical devices
☐ Other

Name and address of MA Holder (Applicant)
Alternative company name

Figure 25 - Cloned Procedural Information

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



Home > Electronic application forms list

Kristiina Puusaari - EMA - pdf post deploy...

Application forms ID: VARI/25/952 | Type: Variation Form Human | Version: 1.2.0.4 | Last saved: 05 Feb 2025, 19:58

Save | Validate | Exports | Refresh | Close

Product selection | Types of changes | **Procedural info** | Proposed changes | Additional info | Finalisation

Procedural info

Type of authorisation
National Procedure

Variation procedure number *
test

Domain *
Human use

Type of application
Single Regulatory Activity
☐ Including a line extension
☐ Worksharing
☒ Super-grouping

Procedure type
Variation Type IAIN

Reference member state *
Ireland

Concerned member states
Cyprus
Estonia
Malta
Poland

Figure 26 - Cloned Procedural Information with Contact Details

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

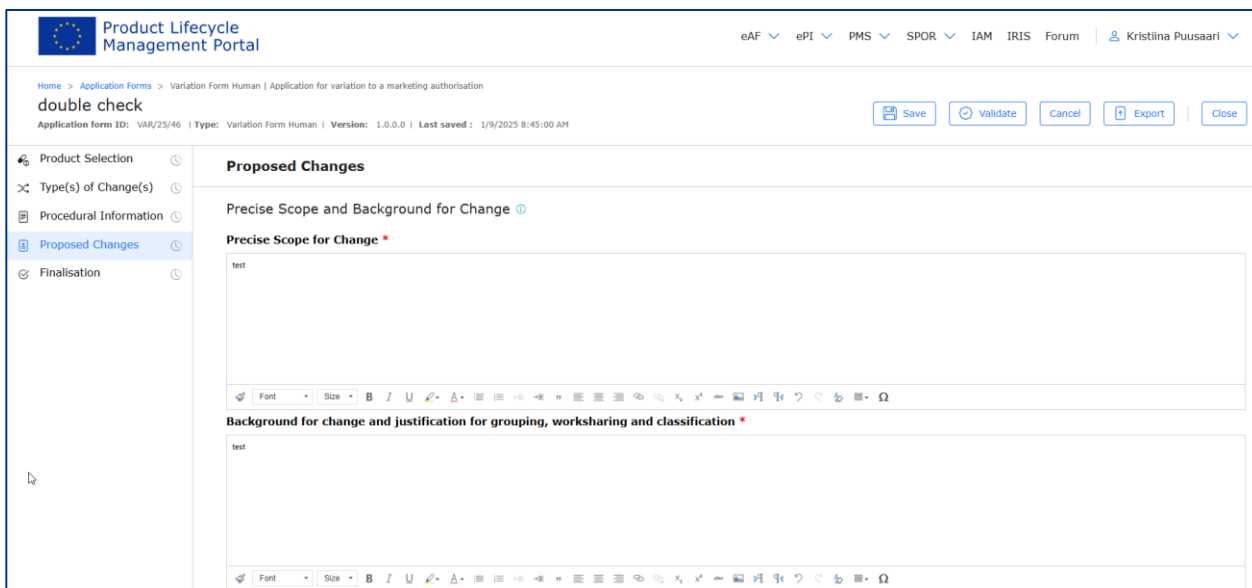


Figure 27 - "Precise Scope" and "Background" Cloned

Present and Proposed Changes

Add changes

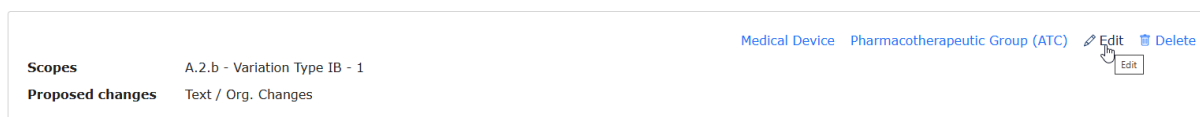


Figure 28 - Present and Proposed Changes

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

2.1.5. Delete form function

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

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

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

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

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

2.1.7. Concurrent users

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

2.2. Product Selection

2.2.1. How to add a product in an Application Form

2.2.1.1. Unfiltered view (adding products without searching)

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

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

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

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

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

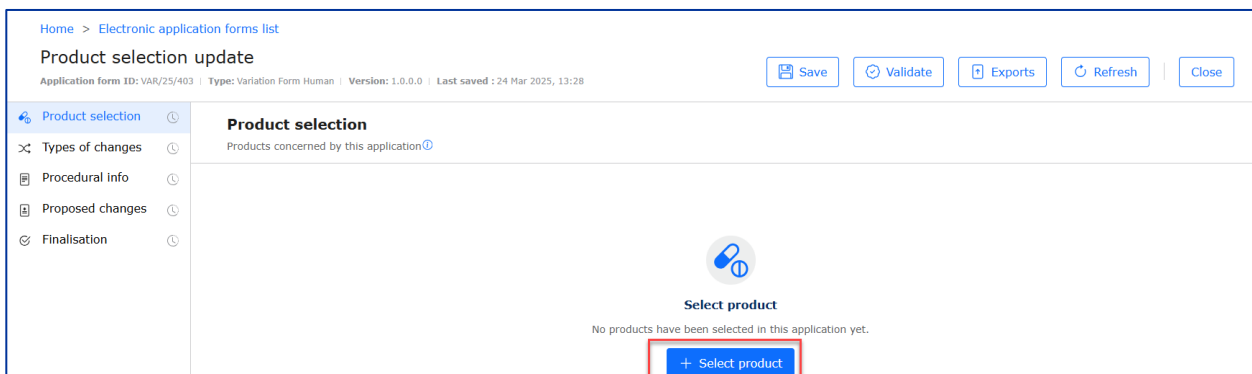


Figure 29 - Add Product

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

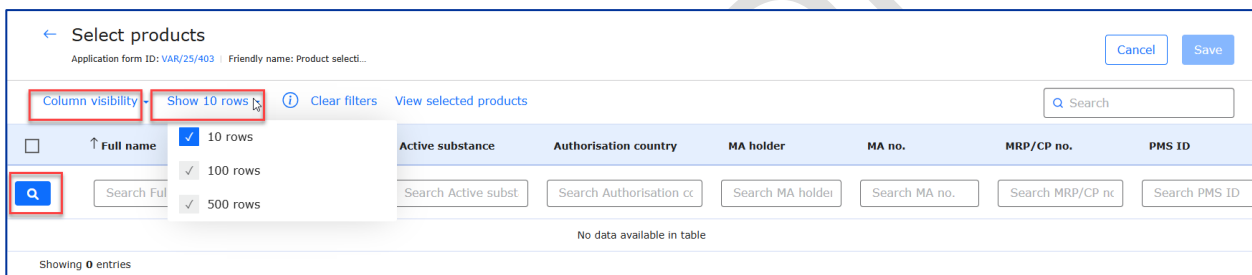



Figure 30 - Column Visibility

- 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.


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

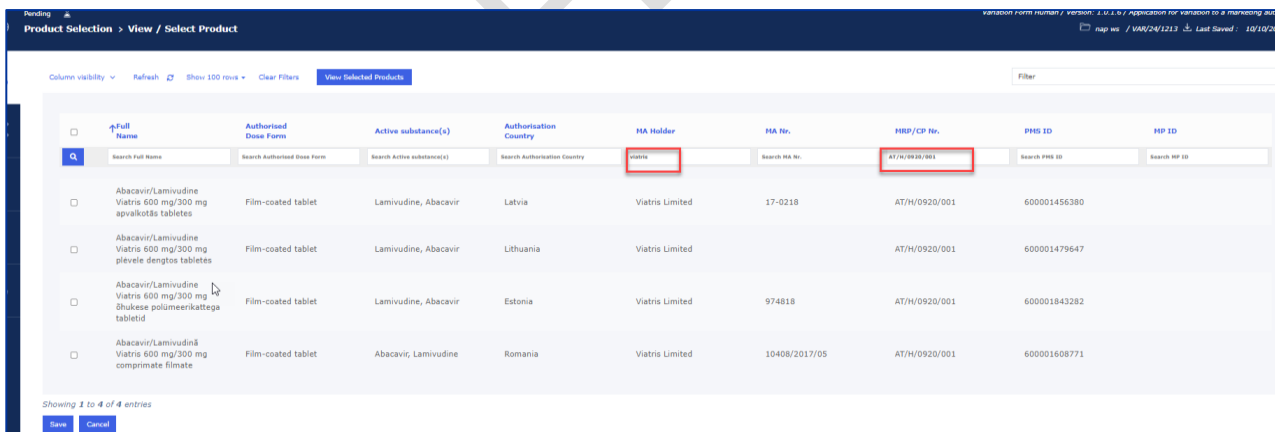


Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.
Dantrium	Powder for solution for injection	Dantrolene sodium	Denmark	Norgine B.V.	10476	
<input checked="" type="checkbox"/> DANTRIUM 100 mg, gélule	Capsule, hard	Dantrolene sodium	France	Norgine B.V.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

Figure 31 - Selecting the Product

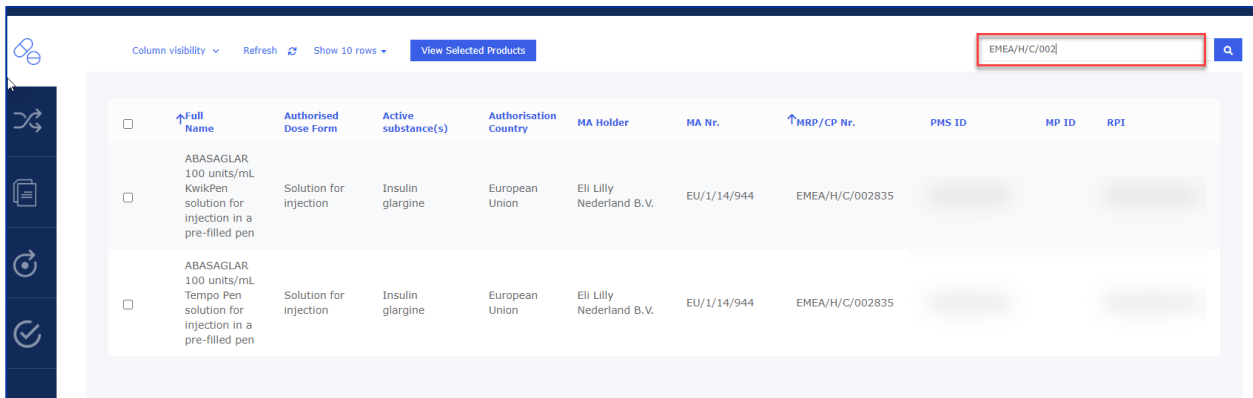
2.2.1.2. Searching and filtering (adding products using search and filter options)

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



Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PHS ID	HP ID
Abacavir/Lamivudine Viatris 600 mg/300 mg apvalkots tablettes	Film-coated tablet	Lamivudine, Abacavir	Latvia	Viatris Limited	17-0218	AT/H/0920/001	600001456380	
Abacavir/Lamivudine Viatris 600 mg/300 mg plėvele dengtos tabletės	Film-coated tablet	Lamivudine, Abacavir	Lithuania	Viatris Limited		AT/H/0920/001	600001479647	
Abacavir/Lamivudine Viatris 600 mg/300 mg Bhukese polimeerikattega tabletid	Film-coated tablet	Lamivudine, Abacavir	Estonia	Viatris Limited	974818	AT/H/0920/001	600001843282	
Abacavir/Lamivudină Viatris 600 mg/300 mg comprimat filmate	Film-coated tablet	Abacavir, Lamivudine	Romania	Viatris Limited	10408/2017/05	AT/H/0920/001	600001608771	

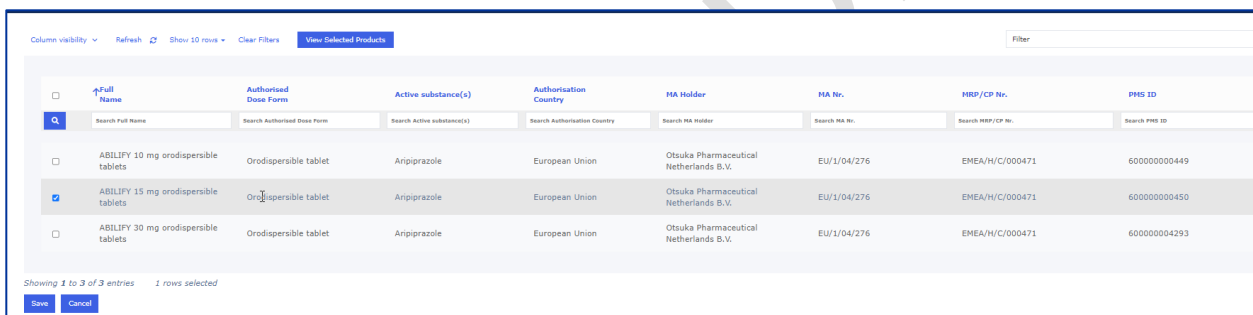
4. It is possible to filter this list to look for the specific product(s) for selection using the field called 'Filter'. The more you type the more the list is filtered.



	Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
<input type="checkbox"/>	ABASAGLAR 100 units/mL 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			
<input type="checkbox"/>	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			

Figure 32 - List of Products

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

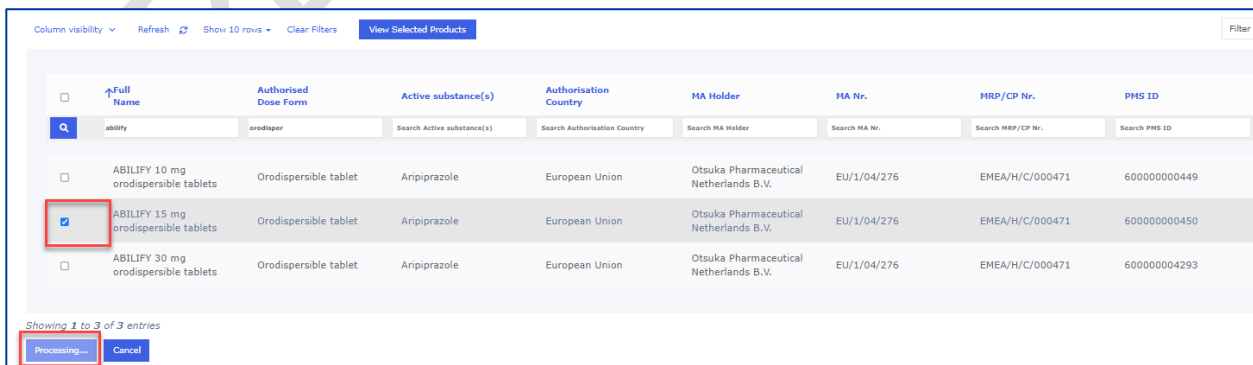


	Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID
<input type="checkbox"/>	ABILIFY 10 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	600000000449
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

Figure 33 - Including Products in the Form

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

- Click on the **Save** button.



	Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS 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	600000000449
<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	600000000450
<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	6000000004293

Figure 34 - Saving

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

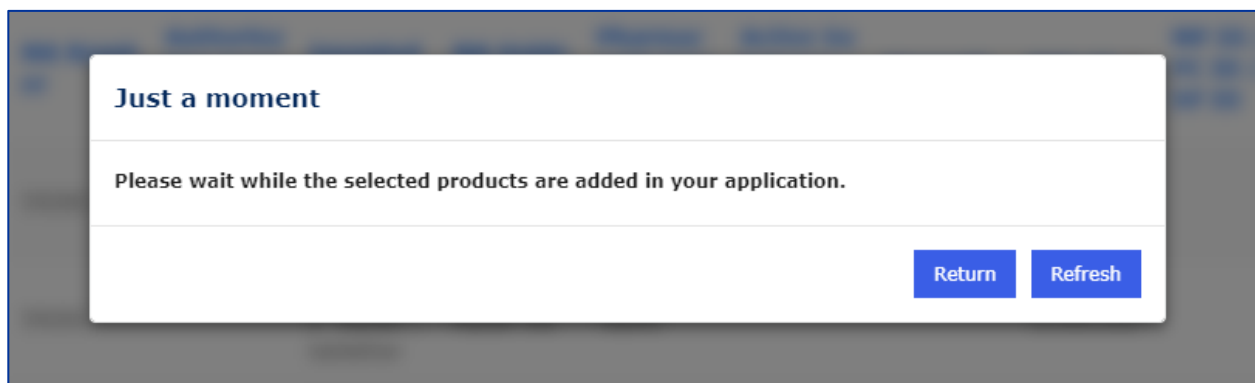


Figure 35 - Adding Products in the Application

- 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 section. **For CAPs only** it is possible to **select only packages that are impacted by the variation**. Also, for CAPs only, it is possible to indicate which packages are impacted by which classification scope.

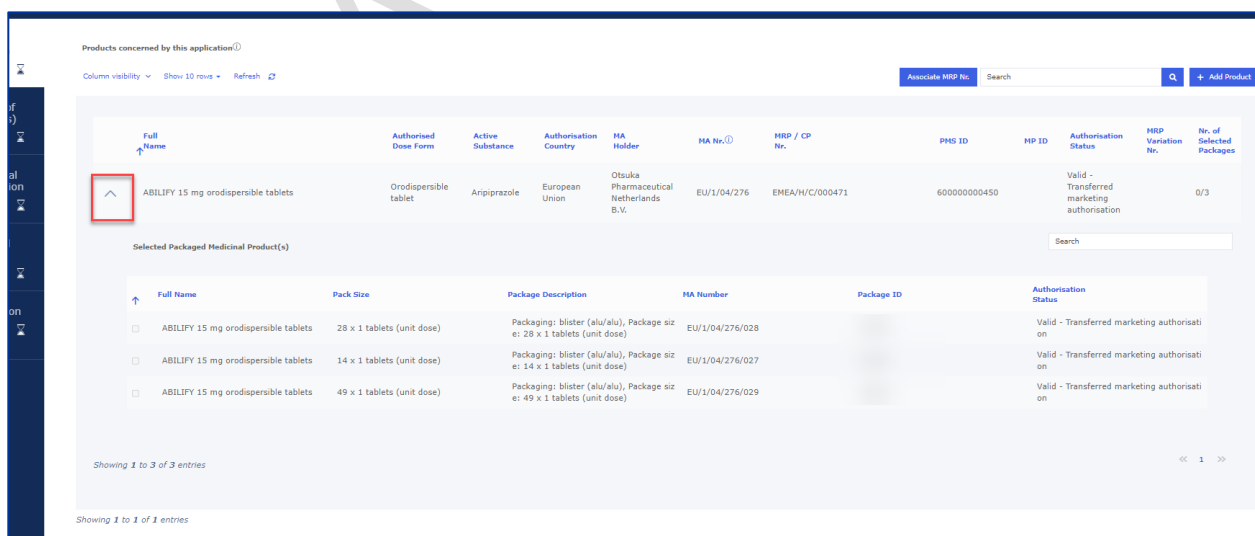


Figure 36 - Expanding view of List Packaged Medicinal products

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

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

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

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

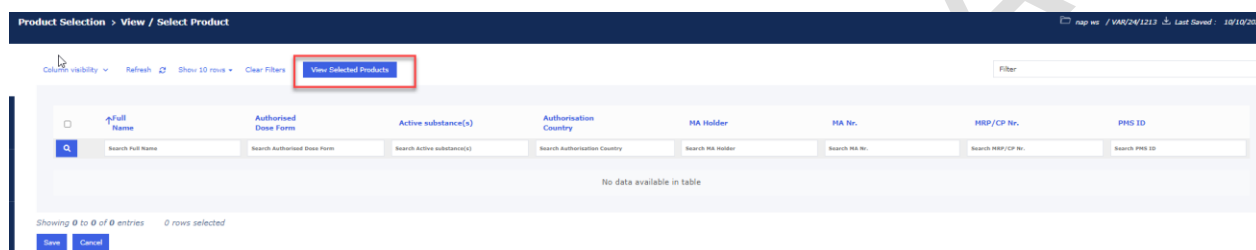


Figure 37 - View selected products

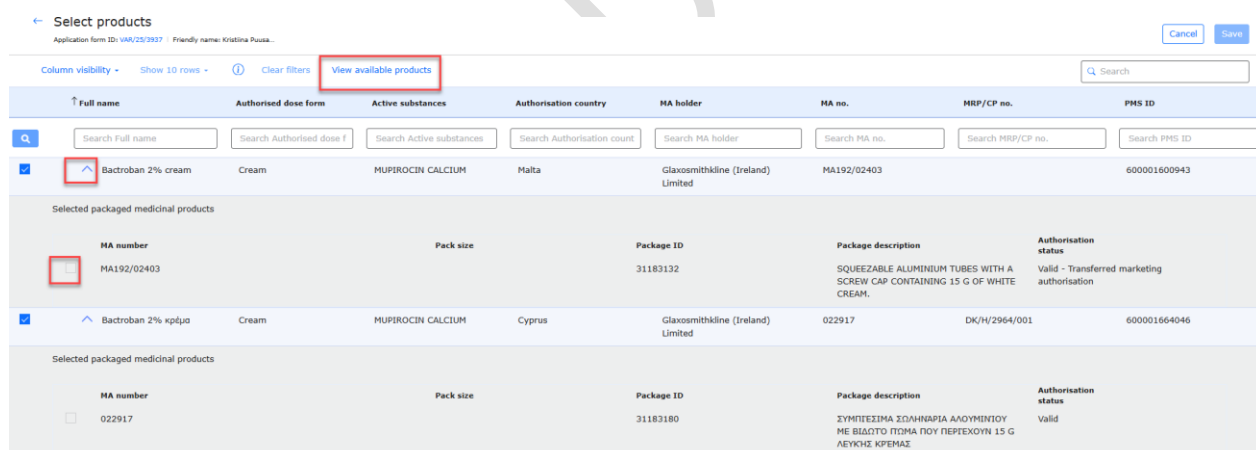


Figure 38 - View Available Products

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

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

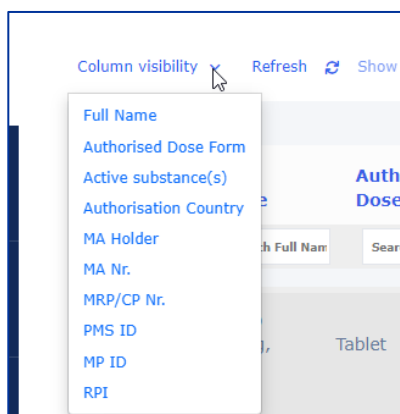


Figure 39 - Column Visibility

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

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

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

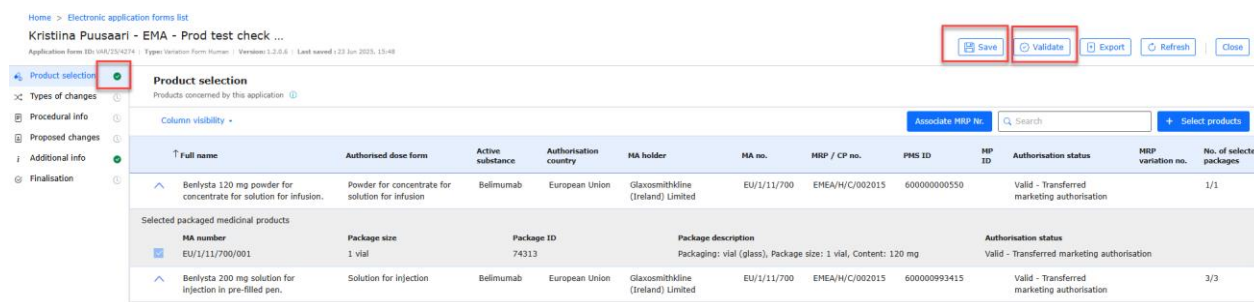
Product selection										
Products concerned by this application										
Column visibility -										
Associate MRP Nr. Search Select products										
Full name	Authorised dose form	Active substance	Authorisation country	MA holder	MA no.	MRP / CP no.	PMS ID	MP ID	Authorisation status	No. of selected packages
Benlysta 120 mg powder for concentrate for solution for infusion.	Powder for concentrate for solution for infusion	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMEA/H/C/002015	600000000550		Valid - Transferred marketing authorisation	1/1
Selected packaged medicinal products										
MA number EU/1/11/700/001	Package size 1 vial	Package ID 74313	Package description Packaging: vial (glass), Package size: 1 vial, Content: 120 mg				Authorisation status Valid - Transferred marketing authorisation			
Benlysta 200 mg solution for injection in pre-filled pen.	Solution for injection	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMEA/H/C/002015	600000993415		Valid - Transferred marketing authorisation	3/3
Selected packaged medicinal products										
MA number EU/1/11/700/003	Package size 1 pre-filled pen	Package ID 30960002	Package description Packaging: pre-filled syringe (glass) in pre-filled pen, Package size: 1 pre-filled pen, Content: 1 ml (200 mg/ml)				Authorisation status Valid - Transferred marketing authorisation			
EU/1/11/700/004	4 pre-filled pens	30960003	Packaging: pre-filled syringe (glass) in pre-filled pen, Package size: 4 pre-filled pens, Content: 1 ml (200 mg/ml)				Valid - Transferred marketing authorisation			
EU/1/11/700/005	12 (3 x 4) pre-filled pens (multipack)	30960004	Packaging: pre-filled syringe (glass) in pre-filled pen, Package size: 12 (3 x 4) pre-filled pens (multipack), Content: 1 ml (200 mg/ml)				Valid - Transferred marketing authorisation			
Benlysta 200 mg solution for	Solution for injection	Belimumab	European Union	Glaxosmithkline	EU/1/11/700	EMEA/H/C/002015	600000993415		Valid - Transferred	3/3

Figure 40 - Packaged Medicinal Product(s)

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

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

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



Home > Electronic application forms list
Kristina Puusaari - EMA - Prod test check ...
Application form ID: 104/23/4214 | Types: Variation Form Number | Version: 1.2.0.0 | Last saved: 23 Jun 2023, 15:48

Product selection
Products concerned by this application

Column visibility

Associate MRP No. Search Select products

Full name	Authorised dose form	Active substance	Authorisation country	MA holder	MA no.	MRP / CP no.	PMS ID	MP ID	Authorisation status	MRP variation no.	No. of selected packages
Benlysta 120 mg powder for concentrate for solution for infusion.	Powder for concentrate for solution for infusion	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMA/H/C/002015	600000000550		Valid - Transferred marketing authorisation		1/1
Selected packaged medicinal products											
MA number	Package size	Package ID	Package description				Authorisation status				
EU/1/11/700/001	1 vial	74313	Packaging: vial (glass), Package size: 1 vial, Content: 120 mg				Valid - Transferred marketing authorisation				
Benlysta 200 mg solution for injection in pre-filled pen.	Solution for injection	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMA/H/C/002015	6000000993415		Valid - Transferred marketing authorisation		3/3

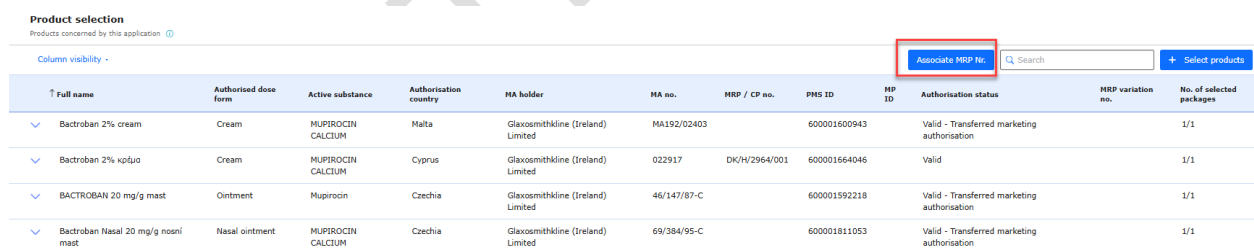
Figure 41 - Save and Validate Buttons

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

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

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

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



Product selection
Products concerned by this application

Column visibility

Associate MRP No. Search Select products

Full name	Authorised dose form	Active substance	Authorisation country	MA holder	MA no.	MRP / CP no.	PMS ID	MP ID	Authorisation status	MRP variation no.	No. of selected packages
Bactroban 2% cream	Cream	MUPIROICIN CALCIUM	Malta	Glaxosmithkline (Ireland) Limited	MA192/02403		600001600943		Valid - Transferred marketing authorisation		1/1
Bactroban 2% xptio	Cream	MUPIROICIN CALCIUM	Cyprus	Glaxosmithkline (Ireland) Limited	022917	DK/H/2964/001	600001664046		Valid		1/1
BACTROBAN 20 mg/g mast	Ointment	Mupirocin	Czechia	Glaxosmithkline (Ireland) Limited	46/147/87-C		600001592218		Valid - Transferred marketing authorisation		1/1
Bactroban Nasal 20 mg/g nosni mast	Nasal ointment	MUPIROICIN CALCIUM	Czechia	Glaxosmithkline (Ireland) Limited	69/384/95-C		600001811053		Valid - Transferred marketing authorisation		1/1

Figure 42 - Associate MRP Nr. Button

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

← Associate MRP number
Application form ID: 6462/2021 | Priority name: Kristina Pava...

MRP Variation Number is updated successfully.

search Column visibility Refresh

Full name	Authorised dose form	Active substance	Authorisation country	MA holder	MA no.	MRP / CP no.	PHS ID	HP ID	MRP Variation no.
BACTROBAN 20 mg/g mast	Ointment	Mupirocin	Czechia	Glaxosmithkline (Ireland) Limited	46/147/87-C		600001592218		
Bactroban 2% xpiuo	Cream	MUPIROCIN CALCIUM	Cyprus	Glaxosmithkline (Ireland) Limited	022917	DK/H/2964/001	600001664046		DK/H/2964/001/WS
Bactroban 2% cream	Cream	MUPIROCIN CALCIUM	Malta	Glaxosmithkline (Ireland) Limited	MA192/02403		600001600943		
Bactroban Nasal 20 mg/g nosni mast	Nasal ointment	MUPIROCIN CALCIUM	Czechia	Glaxosmithkline (Ireland) Limited	69/384/95-C		600001811053		

Showing 4 entries
MRP variation number: DK/H/2964/001/WS

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

Product selection
Products concerned by this application

Column visibility Associate MRP No. Search Select products

Full name	Authorised dose form	Active substance	Authorisation country	MA holder	MA no.	MRP / CP no.	PHS ID	HP ID	Authorisation status	MRP variation no.	No. of selected packages
Bactroban 2% cream	Cream	MUPIROCIN CALCIUM	Malta	Glaxosmithkline (Ireland) Limited	MA192/02403		600001600943		Valid - Transferred marketing authorisation		1/1
Bactroban 2% xpiuo	Cream	MUPIROCIN CALCIUM	Cyprus	Glaxosmithkline (Ireland) Limited	022917	DK/H/2964/001	600001664046		Valid	DK/H/2964/001/WS	1/1
BACTROBAN 20 mg/g mast	Ointment	Mupirocin	Czechia	Glaxosmithkline (Ireland) Limited	46/147/87-C		600001592218		Valid - Transferred marketing authorisation		1/1
Bactroban Nasal 20 mg/g nosni mast	Nasal ointment	MUPIROCIN CALCIUM	Czechia	Glaxosmithkline (Ireland) Limited	69/384/95-C		600001811053		Valid - Transferred marketing authorisation		1/1

Figure 43 - MRP Numbers

5. 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	ENGRIX-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	ENGRIX-B 10 mikrogram/0,5 ml Injeksjonsvæske, suspensjon i ferdigfylt sprøyte Vaksine mot hepatitt B (rdna) (adsorbent)	Glaxosmithkline AS	Norway	Suspension for injection in pre-filled syringe

Figure 44 - MRP Variation Number

2.2.1.4. How to delete a product from an Application Form

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

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

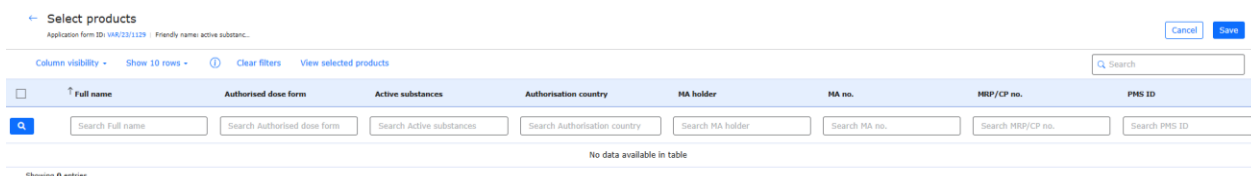
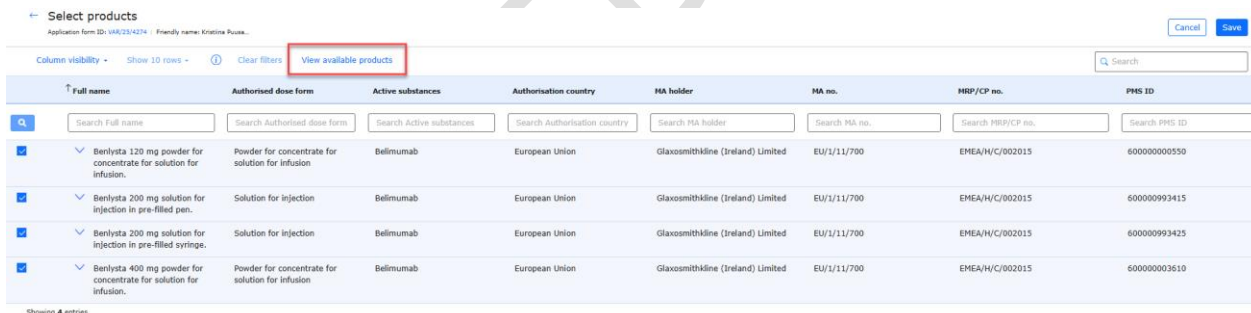


Figure 45 - Add Product

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

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



	Full name	Authorised dose form	Active substances	Authorisation country	MA holder	MA no.	MRP/CP no.	PMS ID
<input checked="" type="checkbox"/>	Benlysta 120 mg powder for concentrate for solution for infusion.	Powder for concentrate for solution for infusion	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMEA/H/C/002015	600000000550
<input checked="" type="checkbox"/>	Benlysta 200 mg solution for injection in pre-filled pen.	Solution for injection	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMEA/H/C/002015	6000000993415
<input checked="" type="checkbox"/>	Benlysta 200 mg solution for injection in pre-filled syringe.	Solution for injection	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMEA/H/C/002015	6000000993425
<input checked="" type="checkbox"/>	Benlysta 400 mg powder for concentrate for solution for infusion.	Powder for concentrate for solution for infusion	Belimumab	European Union	Glaxosmithkline (Ireland) Limited	EU/1/11/700	EMEA/H/C/002015	6000000003510

Figure 46 - View Available Products

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

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

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

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

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

Known limitations:

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

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

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

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

2.3. Type(s) of change(s)

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

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

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

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

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

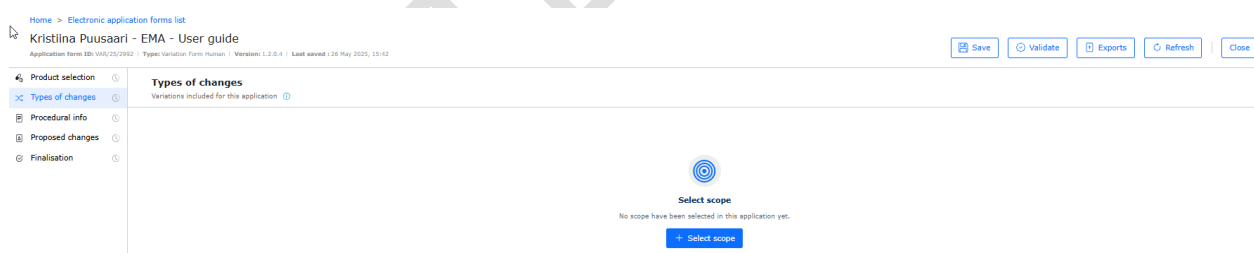


Figure 47 - Select Scope


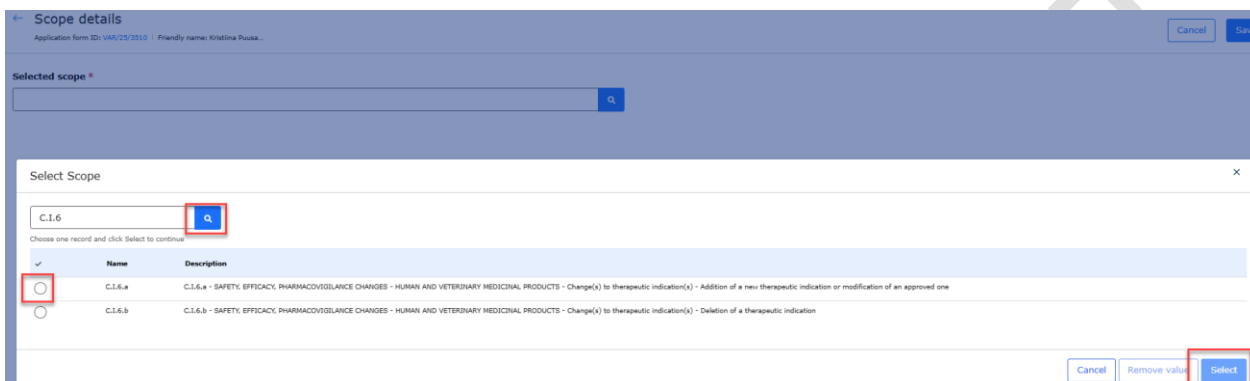
3. In the Select/Edit Scope subpage, launch the search for scope (variation classification category) selection by clicking on the magnifying glass . The scopes (categories) cannot be searched in Select/Edit scope subpage. Clicking the magnifying glass will open the 'Select scope window where you can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



Figure 48 - Select Scope

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

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



Scope details
Application form ID: VAA/23/2510 | Friendly name: Kristina Pusa...

Selected scope *

Select Scope

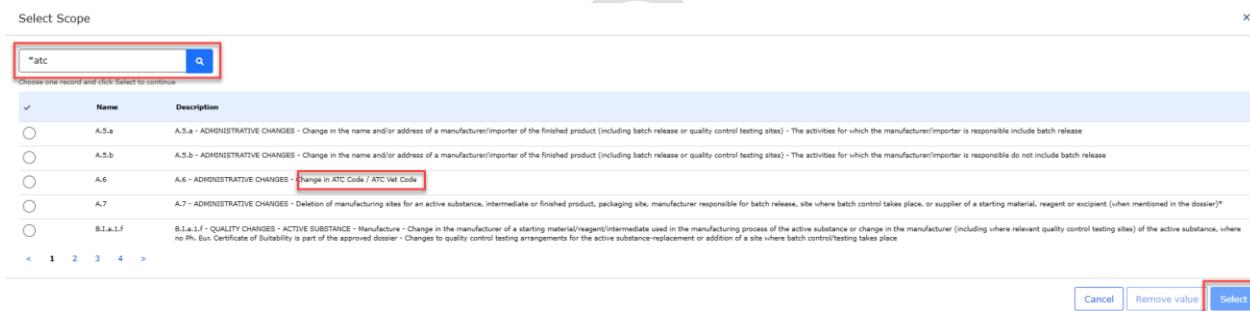
C.I.6

Choose one record and click Select to continue

	Name	Description
<input checked="" type="radio"/>	C.I.6.a	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
<input type="radio"/>	C.I.6.b	C.I.6.b - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication

Cancel Remove value Select

Figure 49 - Example of Search using Classification Code



Select Scope

*atc


Choose one record and click Select to continue

	Name	Description
<input checked="" type="radio"/>	A.5.a	A.5.a - 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 include batch release
<input type="radio"/>	A.5.b	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
<input type="radio"/>	A.6	A.6 - ADMINISTRATIVE CHANGES - Change in ATC Code / ATC Val Code
<input type="radio"/>	A.7	A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*
<input type="radio"/>	B.I.a.1.f	B.I.a.1.f - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place

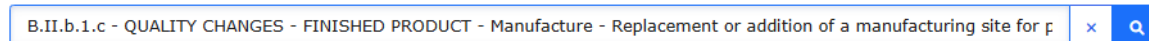
Cancel Remove value Select

Figure 50 - Example of Search using Wild Card and Text

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

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

Selected scope *



B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for p

Figure 51 - Cancel and Select Scope

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

Selected scope *

B.II.b.1.c - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for p

Procedure type *

Identifier *

Select procedure type from the list

Figure 52 - Select Procedure Type

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

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

Selected scope *

B.II.b.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements ar

Procedure type *

Select Procedure Type

Search

Choose one record and click Select to continue

	Name ↑
<input checked="" type="radio"/>	Variation Type 1A2H
<input type="radio"/>	Variation Type 1B

Cancel Remove value **Select**

Figure 53 - Select Procedure Type

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

Selected scope *
B.II.3.2.c.1 - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer; batch release arrangements and quality control testing of th

Procedure type *
Variation Type IARIN

Identifier *
B.II.3.2.c.1 - Variation Type IARIN - 1

Implementation Date *
30/05/2025

Implementation Date Note

Compliance with condition for scope *
If not compliant, select No and provide reason.

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

☒ Yes ☐ No

Note
Text here

2. The manufacturer responsible for batch release must be located within the EU/EEA. At least one batch release site remains within the EU/EEA that is able to certify the product testing for the purpose of batch release within the EU/EEA.

☒ Yes ☐ No

Reason
Must add text if option 'No' is selected

3. The site is appropriately authorised.

☒ Yes ☐ No

Documentations present for scope *
If not present, select No and provide reason.

1. A declaration by the Qualified Person (QP) responsible for batch certification stating that the active substance manufacturer(s) referred to in the marketing authorisation operate in compliance with the detailed guidelines on good manufacturing practice for starting materials. A single declaration may be acceptable under certain circumstances – see the note under variation No. B.II.3.1.

☒ Yes ☐ No

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

☒ Yes ☐ No

Figure 54 - Option Selection

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

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

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

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

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

Types of changes
Variations included for this application

Search Select scope

Scope	Selected	Description	Action
B.1.b.2.a Minor changes to an approved test procedure	1	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	Action
B.1.b.2.a - Variation Type IB - 1	Variation Type IB			N/A	Clone scope

Condition

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.

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).

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).

There have been no changes of the total impurity limits; no new unqualified impurities are detected.

Documentation

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).

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 clone scope image at the far right of the same row to select "Clone scope" option.

Types of changes
Variations included for this application

Search Select scope

Scope	Selected	Description	Action
B.1.b.2.a Minor changes to an approved test procedure	1	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	Action
B.1.b.2.a - Variation Type IB - 1	Variation Type IB			N/A	Clone scope

Condition

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.

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).

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).

There have been no changes of the total impurity limits; no new unqualified impurities are detected.

Documentation

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).

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.

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

Types of changes
Variations included for this application

Scope	Selected	Description	Action
B.1.b.2.a Minor changes to an approved test procedure	2	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	Action
B.1.b.2.a - Variation Type IB - 2	Variation Type IB			N/A	
B.1.b.2.a - Variation Type IB - 1	Variation Type IB			N/A	

- 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.

Scope	Selected	Description	Action
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	Action
B.1.b.2.a - Variation Type IB - 2	Variation Type IB			N/A	
B.1.b.2.a - Variation Type IB - 1	Variation Type IB			N/A	
B.1.b.2.a - Variation Type IB - 3	Variation Type IB			N/A	

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.

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

Scope	Selected	Description	Action
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	Action
B.1.b.2.a - Variation Type IB - 2	Variation Type IB			N/A	
B.1.b.2.a - Variation Type IB - 1	Variation Type IB			N/A	
B.1.b.2.a - Variation Type IB - 3	Variation Type IB			N/A	

Product Selection
 Pending

Type(s) of Change(s)
 Pending

Procedural Information
 Pending

Variations included for this application

Refresh

Scope	Selected	Description	Action
B.1.b.2.a Minor changes to an approved test procedure	1	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	

Save Validate Cancel Export

Figure 57 - Delete Scope

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

↑ Scope	Selected	Description	Action
^ 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	
▼ B.1.b.2.a - Variation Type IB - 2			✎ 📄 🗑️
▼ B.1.b.2.a - Variation Type IB - 1			✎ 📄 🗑️
▼ B.1.b.2.a - Variation Type IB - 3			✎ 📄 🗑️

Figure 58 - Edit Scope

2.3.4. How to delete a scope in an application

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

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

↑ Scope	Selected	Description	Action
^ 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	✎ 📄 🗑️
▼ B.1.b.2.a - Variation Type IB - 2			✎ 📄 🗑️
▼ B.1.b.2.a - Variation Type IB - 1			✎ 📄 🗑️
▼ B.1.b.2.a - Variation Type IB - 3			✎ 📄 🗑️
^ C.1.6.a Addition of a new therapeutic indication or modification of an approved one	1	C.1.6.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	✎ 📄 🗑️

Figure 59 - Delete Scope

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

↑ Scope	Selected	Description	Action
^ 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	
▼ B.1.b.2.a - Variation Type IB - 2			✎ 📄 🗑️
▼ B.1.b.2.a - Variation Type IB - 1			✎ 📄 🗑️
▼ B.1.b.2.a - Variation Type IB - 3			✎ 📄 🗑️
^ C.1.6.a Addition of a new therapeutic indication or modification of an approved one	1	C.1.6.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	
▼ C.1.6.a - Variation Type II - 1			✎ 📄 🗑️

Figure 60 - Edit Scope

2.4. Procedural Information

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

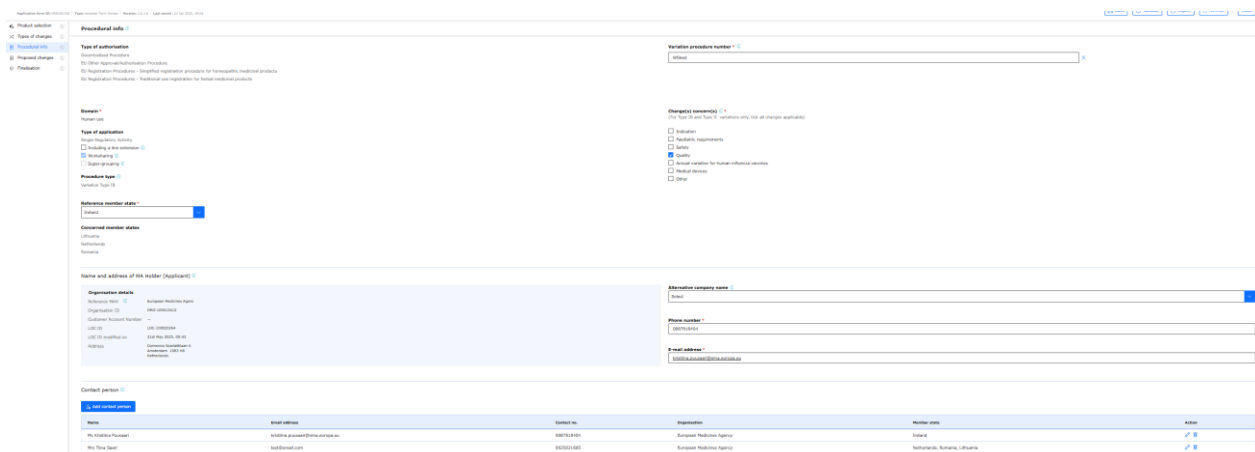


Figure 61 - Procedural Information Section Overview

2.4.1. Procedural Information

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

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

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

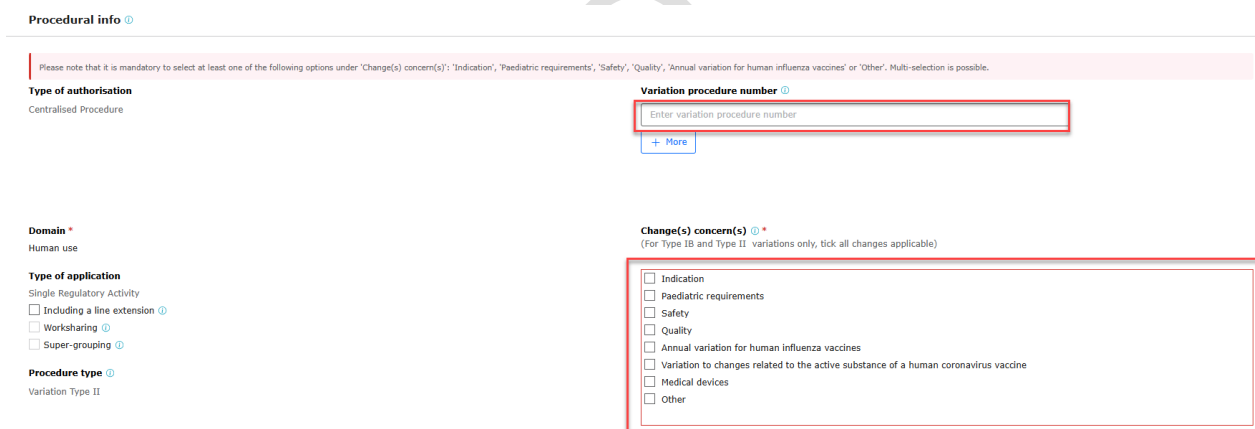


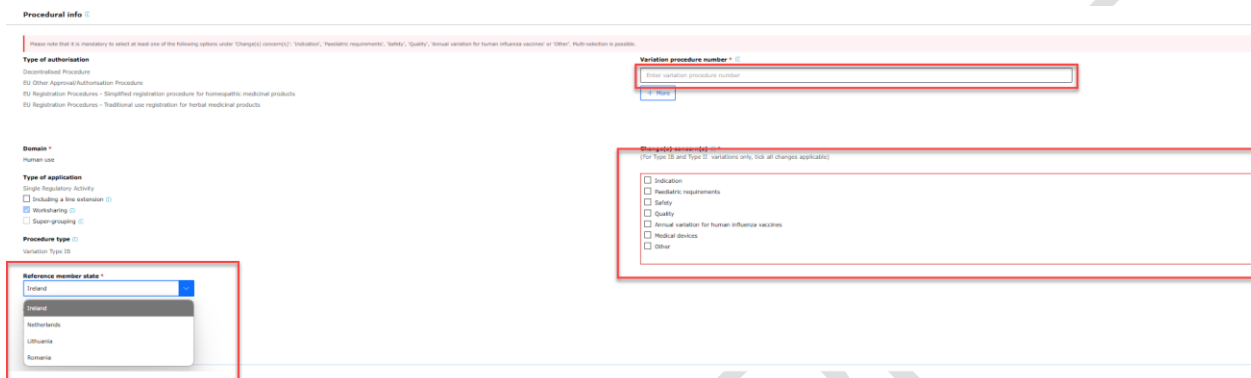
Figure 62 - Sub-section: Procedural Information

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

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

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

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



Procedural info

Please note that it is mandatory to select at least one of the following options under 'Change(s) concern(s)'. Indication, Pediatric requirements, Safety, Quality, Annual variation for human influenza vaccines, or Other. Multi-selection is possible.

Type of authorisation
 Registration Procedure
 EU Other Approval/Authorisation Procedure
 EU Registration Procedure - Simplified registration procedure for homeopathic medicinal products
 EU Registration Procedure - Traditional use registration for herbal medicinal products

Domain
 Human use

Type of application
 Single Regulatory Activity
☐ Including in the extension
☒ Worksharing
☐ Super-grouping

Procedure type
 Variation Type IB

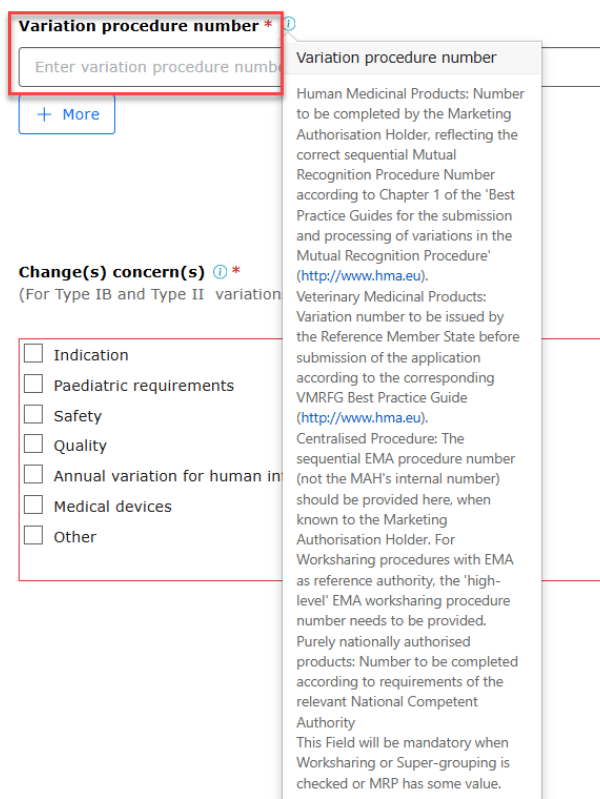
Reference member state
 Ireland
 Ireland
 Netherlands
 Lithuania
 Romania

Variation procedure number
 Enter variation procedure number
 Add New

Change(s) concern(s)
 (For Type IB and Type II variations only, tick all changes applicable)
☐ Indication
☐ Pediatric requirements
☐ Safety
☐ Quality
☐ Annual variation for human influenza vaccines
☐ Medical devices
☐ Other

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

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



Variation procedure number *

Enter variation procedure number

[+ More](#)

Change(s) concern(s) *
(For Type IB and Type II variation)

- ☐ Indication
- ☐ Paediatric requirements
- ☐ Safety
- ☐ Quality
- ☐ Annual variation for human in
- ☐ Medical devices
- ☐ Other

Variation procedure number

Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential Mutual Recognition Procedure Number according to Chapter 1 of the 'Best Practice Guides for the submission and processing of variations in the Mutual Recognition Procedure' (<http://www.hma.eu>).

Veterinary Medicinal Products: Variation number to be issued by the Reference Member State before submission of the application according to the corresponding VMRF Best Practice Guide (<http://www.hma.eu>).

Centralised Procedure: The sequential EMA procedure number (not the MAH's internal number) should be provided here, when known to the Marketing Authorisation Holder. For Worksharing procedures with EMA as reference authority, the 'high-level' EMA worksharing procedure number needs to be provided.

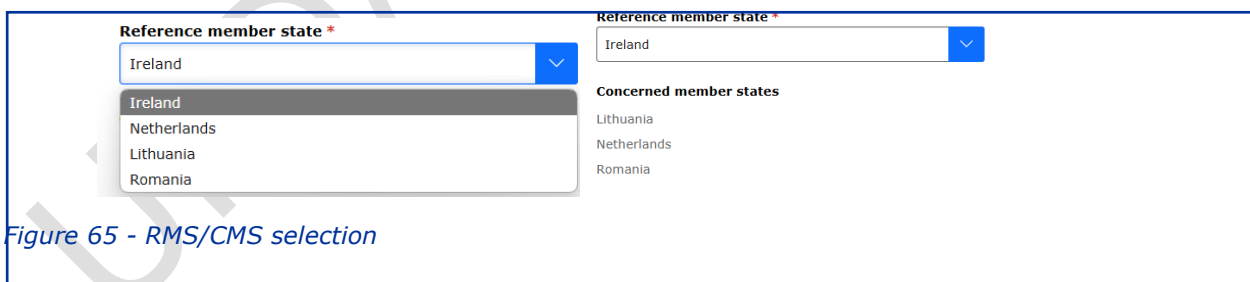
Purely nationally authorised products: Number to be completed according to requirements of the relevant National Competent Authority

This Field will be mandatory when Worksharing or Super-grouping is checked or MRP has some value.

Figure 64 - Variation Procedure Number

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

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



Reference member state *

Ireland

Concerned member states

Lithuania
Netherlands
Romania

Figure 65 - RMS/CMS selection

2.4.2. Name and Address of MA Holder (Applicant)

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

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

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

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

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

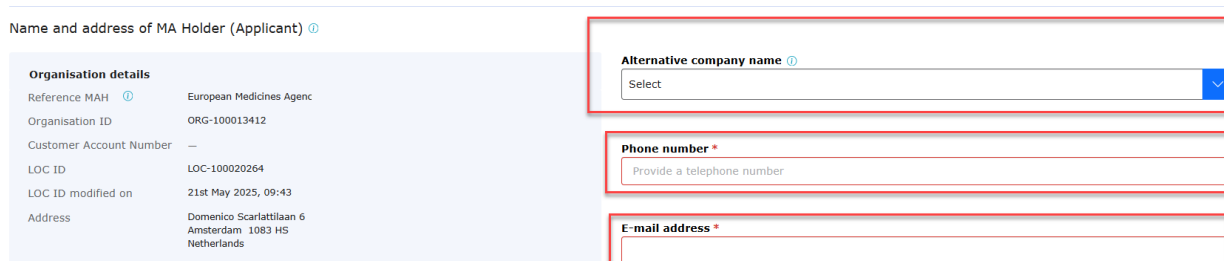


Figure 66 - Name and Address of MA Holder (Applicant)

2.4.3. Contact Person

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

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

1. Click the **+ Add** button

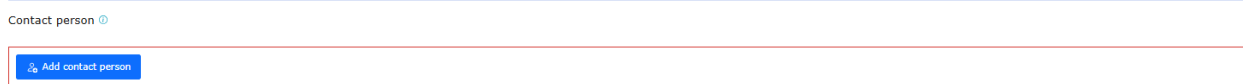


Figure 67 - Contact Person

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

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

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

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

Add contact person ×

Member State *

Netherlands × Ireland ×

✓ Netherlands
✓ Ireland
Romania
Lithuania
Provide a telephone number


Company *

Title

Surname *


E-mail address *

Figure 68 - Create Application Contact

- 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

First name * Surname *

Select Company ×

 Search Results

Choose one record and click Select to continue

	Organisation Name ↑	Full address	Organisation Id	Organisation Location
<input checked="" type="radio"/>	Terveysten Ja Hyvinvoinnin Laitos	Mannerheimintie 156 00300 Helsinki Helsinki-Uusimaa Finland	ORG-100019555	LOC-100039037
<input type="radio"/>	Terveysten Ja Hyvinvoinnin Laitos	PI 30 00271 Helsinki Finland	ORG-100019555	LOC-100039039
<input type="radio"/>	Työterveyslaitos	Topeliuksenkatu 41b 00250 Helsinki Finland	ORG-100022861	LOC-100031573

Figure 69 - Lookup Records

- 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

Add contact person ×

Member State *

Netherlands × Ireland × ⌵

First name *

Phone number *

Provide a telephone number

Company *

Terveystieteiden tutkimuskeskus × 🔍

Title

Surname *

E-mail address *

Organisation details

Organisation ID	ORG-100019555
Customer Account Number	—
LOC ID	LOC-100039039
LOC ID modified on	13th Jul 2022, 14:02
Address	PI 30 Helsinki 00271 Finland

Cancel
Done

Figure 70 - Contact Person Details

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

2.5. Proposed Changes

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

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

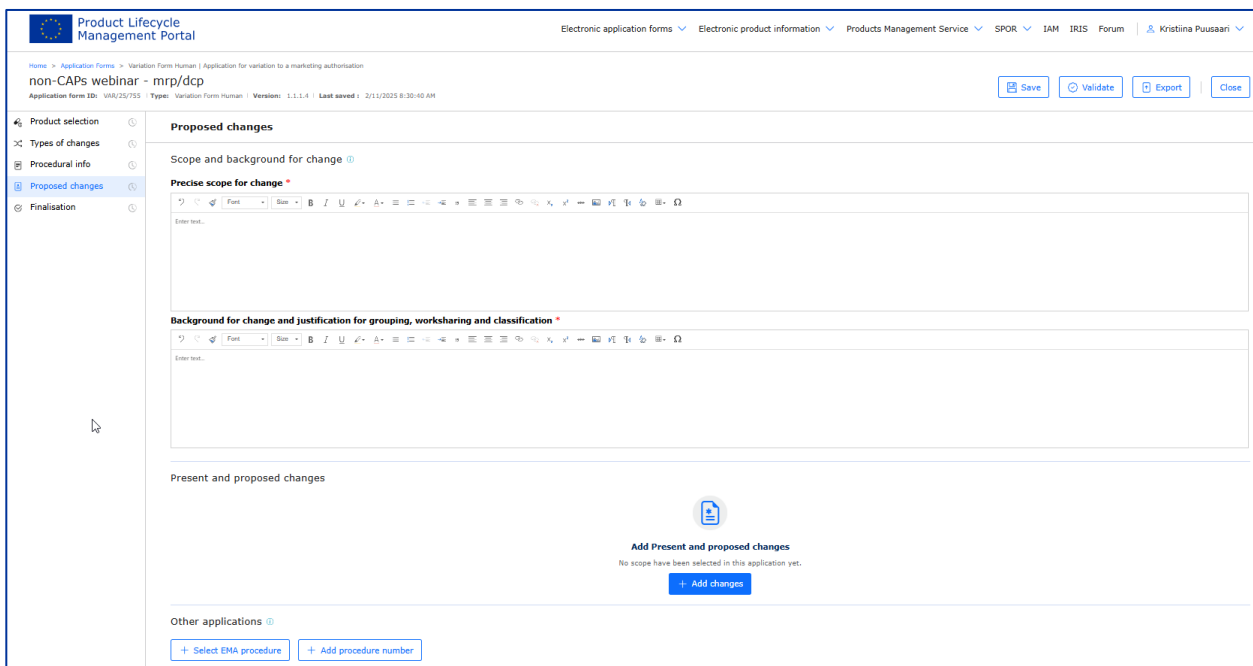


Figure 71 - Proposed Changes

2.5.1. Precise Scope and Background for Change

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

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

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

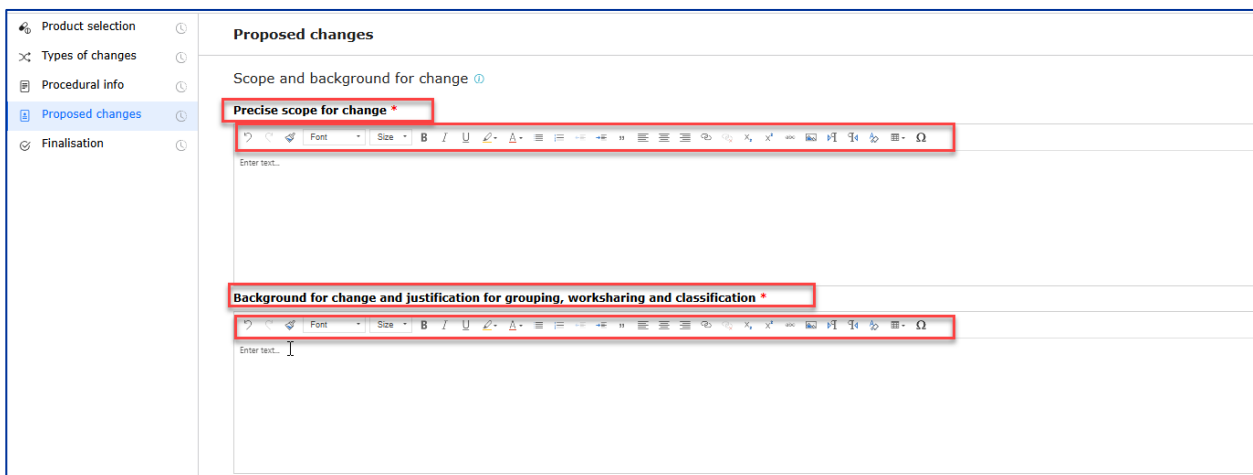


Figure 72 - Precise Scope and Background for Change

2.5.2. Present and Proposed Changes

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

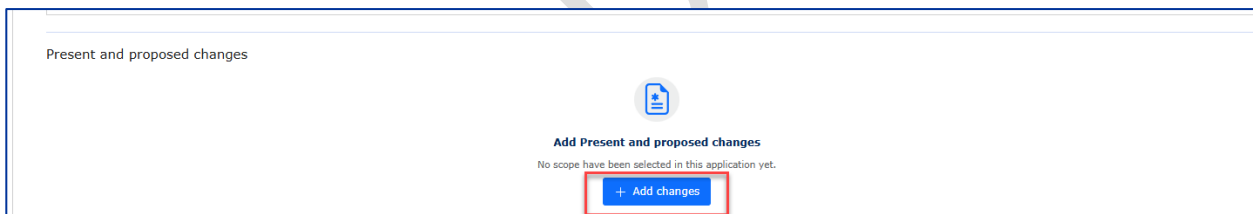
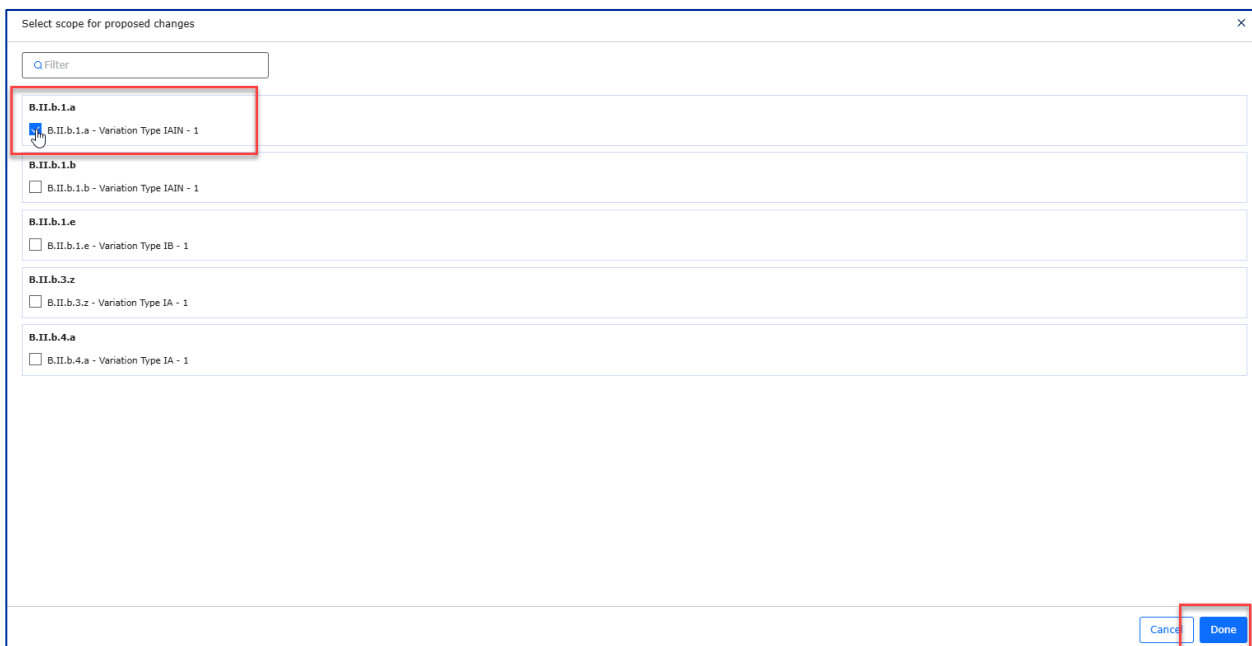


Figure 73 - Proposed Changes

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

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



Select scope for proposed changes

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

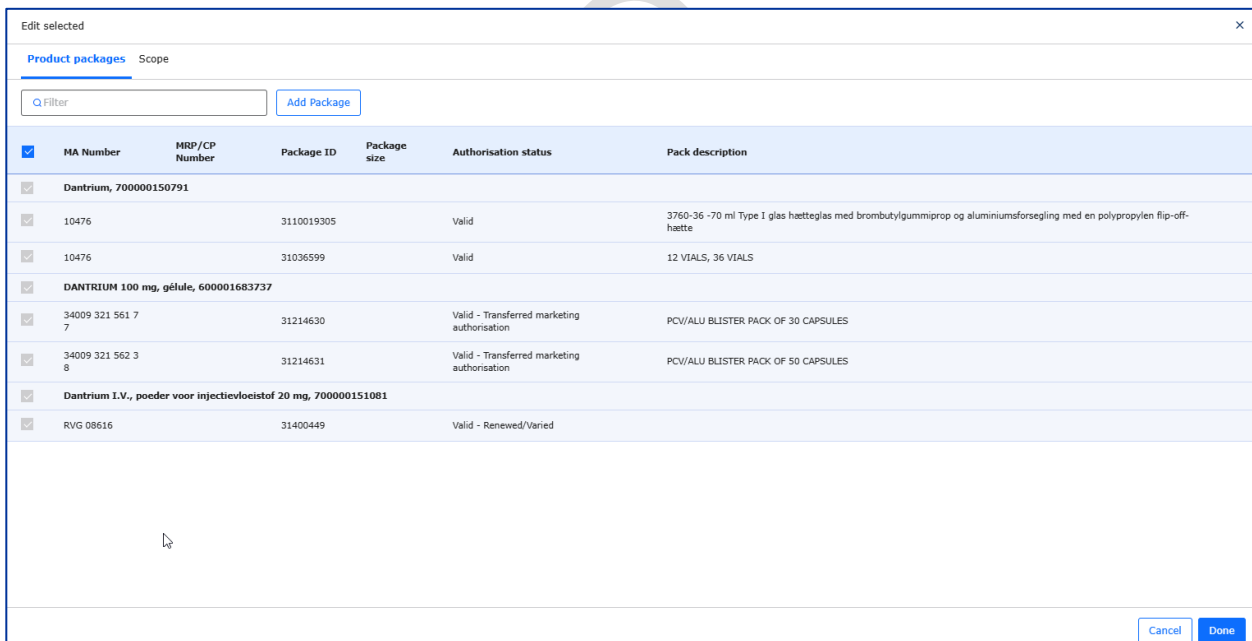
☐ B.II.b.3.z - Variation Type IA - 1

☐ B.II.b.4.a - Variation Type IA - 1

Cancel Done

Figure 74 - Selection of Scope and Medicinal Product

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



Edit selected

Product packages Scope

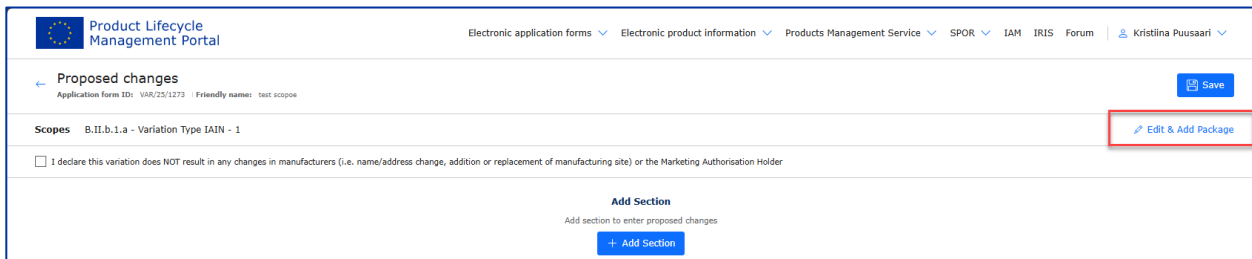
Filter Add Package

<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	3760-36 -70 ml Type I glas hætteglas med brombutylgumprop og aluminiumsforsøgning 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

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

4. For **CAPs only**: the packages can be selected separately e.g. if the variation only impacts certain packages/pack-sizes, it is possible to select only those packages/pack-sizes relevant to each scope. This is an important step as the **selections of the Packaged Medicinal Products in this section defines which MA numbers are listed in section 2 of pdf** output form.
 - a. All packages are initially auto-selected, however it is possible to edit the selection for CAPs by clicking the 'Edit and add package' button'.



Product Lifecycle Management Portal

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

← 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

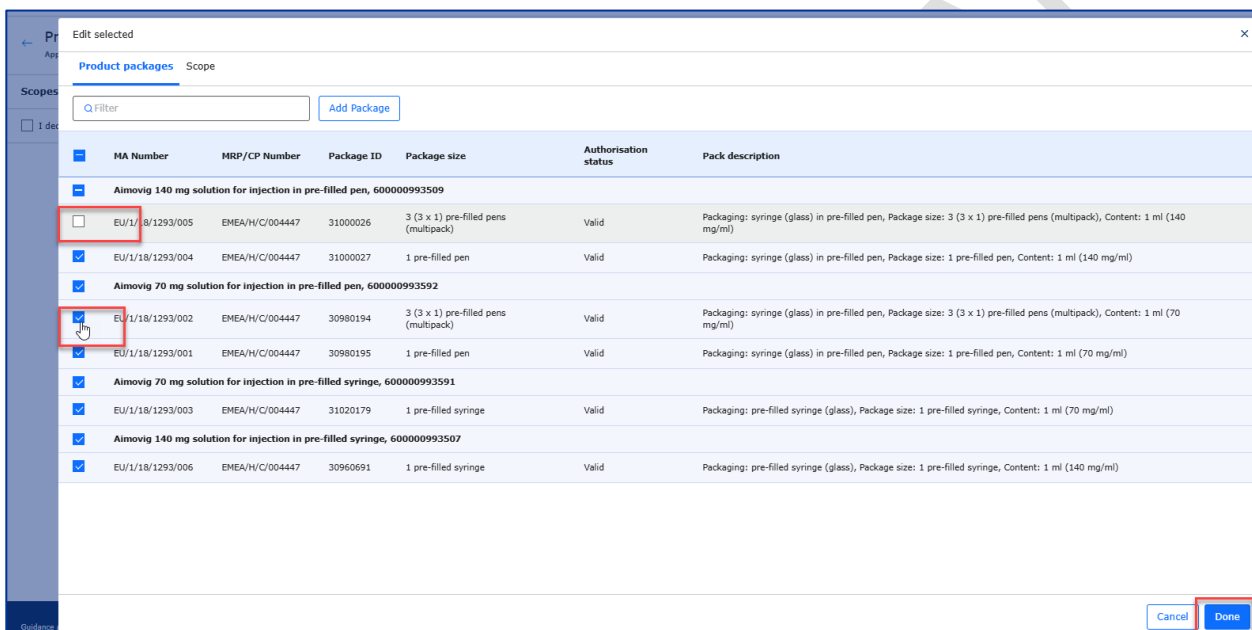
+ Add Section

Save

Edit & Add Package

Figure 76 - Linking CAP Packages to Scopes

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



Edit selected

Product packages Scope

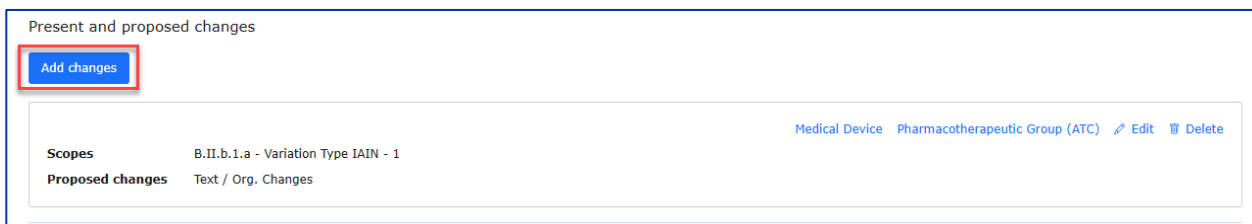
Filter Add Package

	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/1/8/1293/005	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

Figure 77 - Deselecting packaged medicinal products

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



Present and proposed changes

Add changes

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

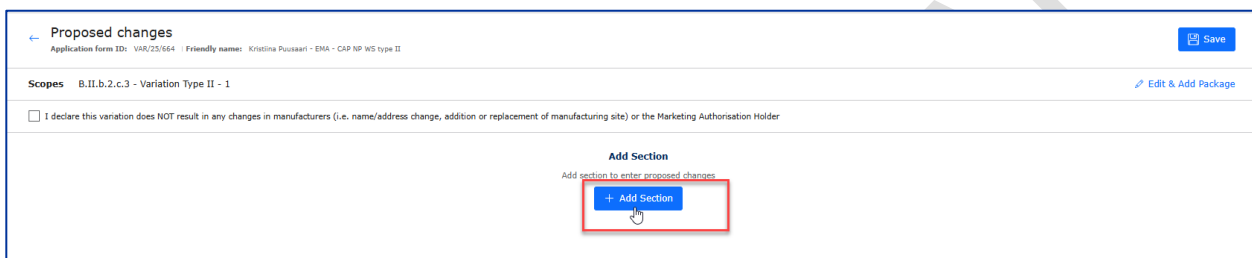
Proposed changes Text / Org. Changes

Medical Device Pharmacotherapeutic Group (ATC) Edit Delete

Figure 78 - Add 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.



Proposed changes

Application form ID: VAR/25/664 | Friendly name: Kristina Puusaari - EMA - CAP NP WS type II

Scopes B.II.b.2.c.3 - Variation Type II - 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

Figure 79 - 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.

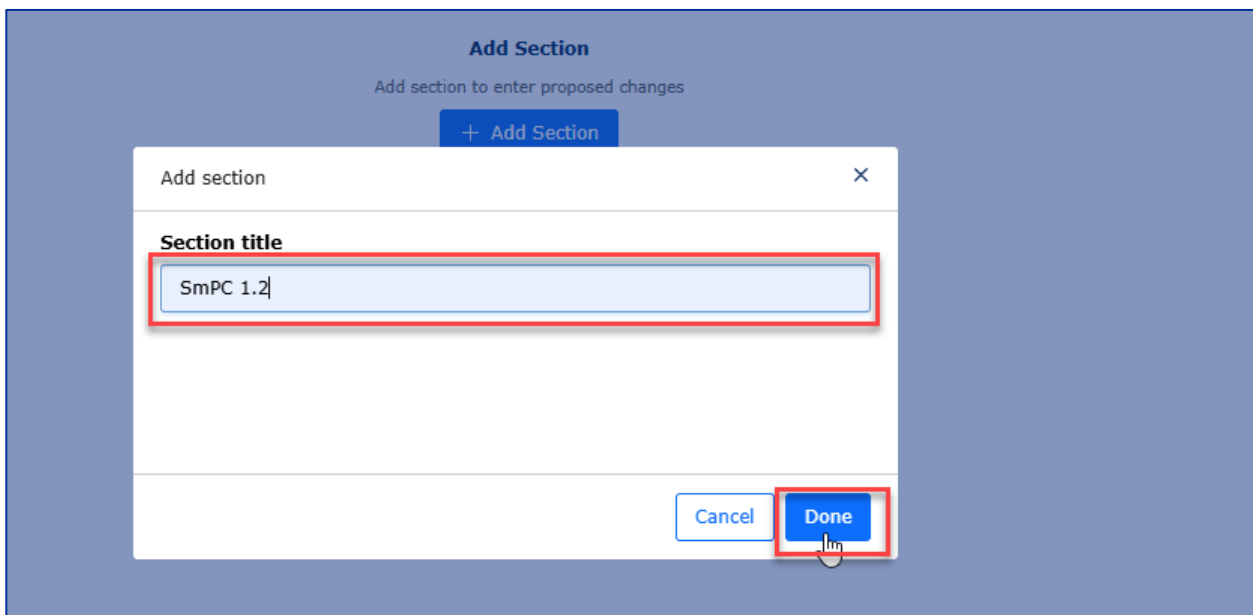


Figure 80 - Section Title Example

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

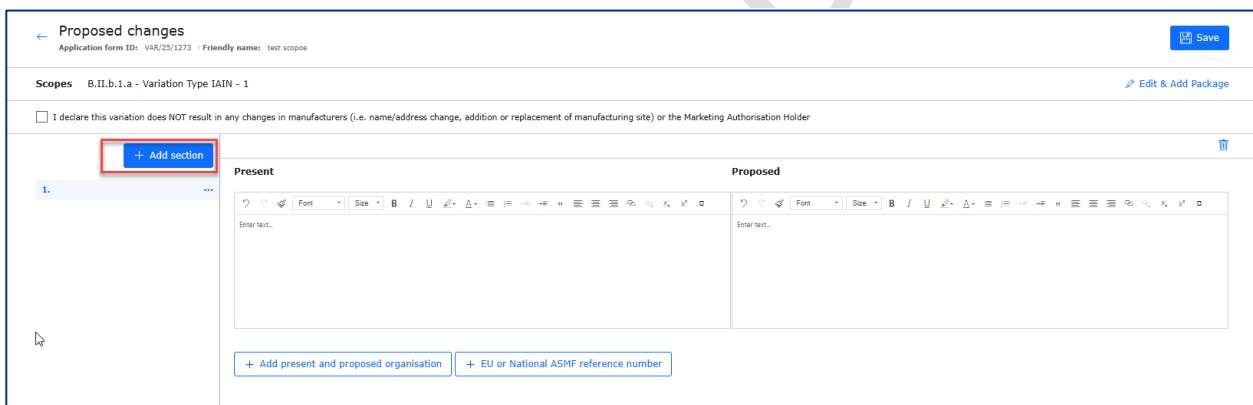


Figure 81 - Adding sections

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

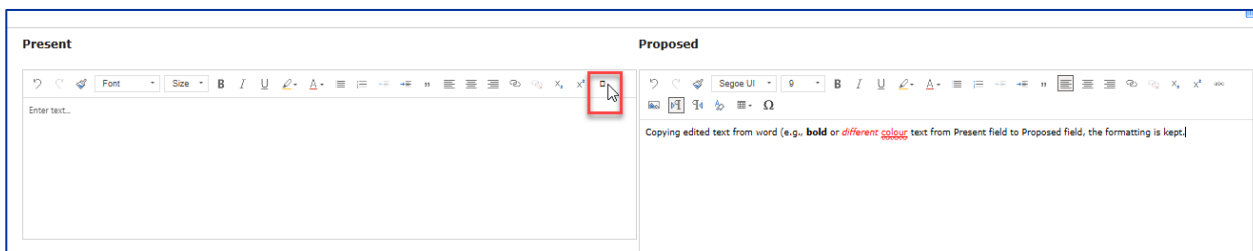


Figure 82 - Editing Present and Proposed Fields

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

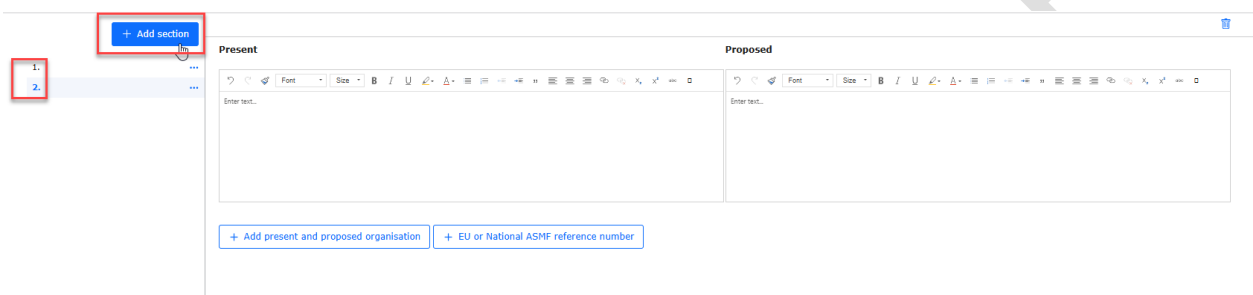


Figure 83 - Add Sections

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

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

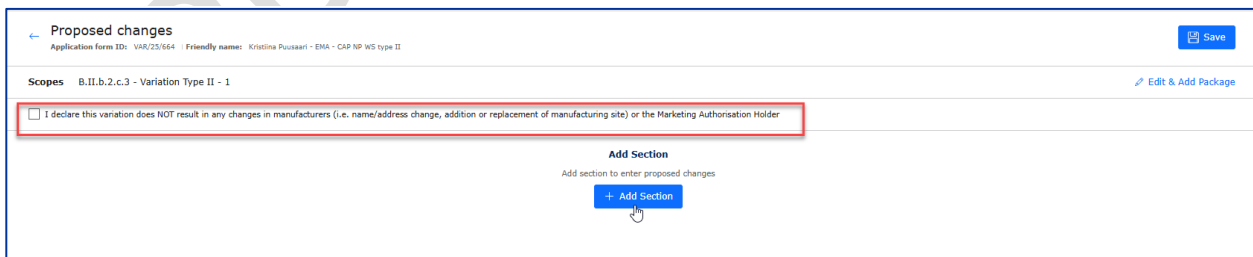


Figure 84 - Mandatory Use of OMS For CAPs

2.5.2.3. Organisation Details

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

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

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

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

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

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

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

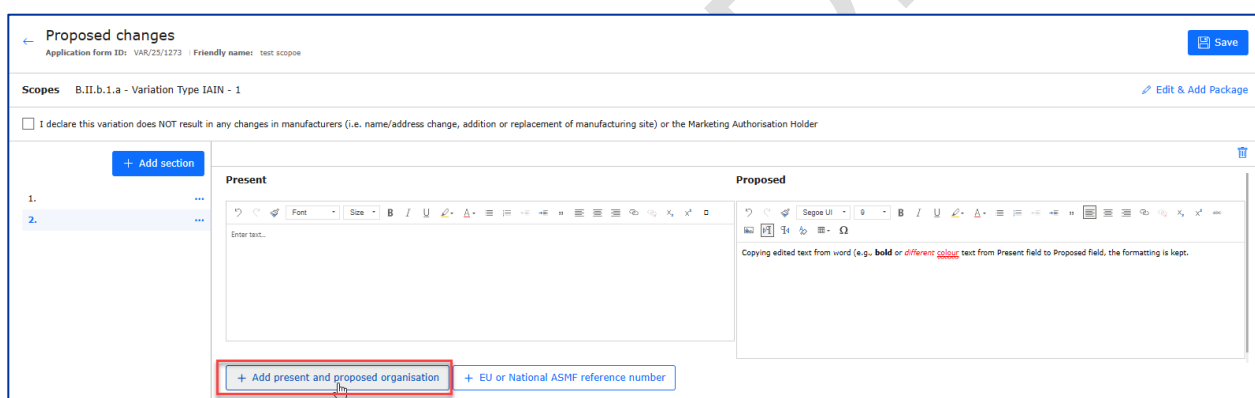



Figure 85 - OMS Changes

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

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

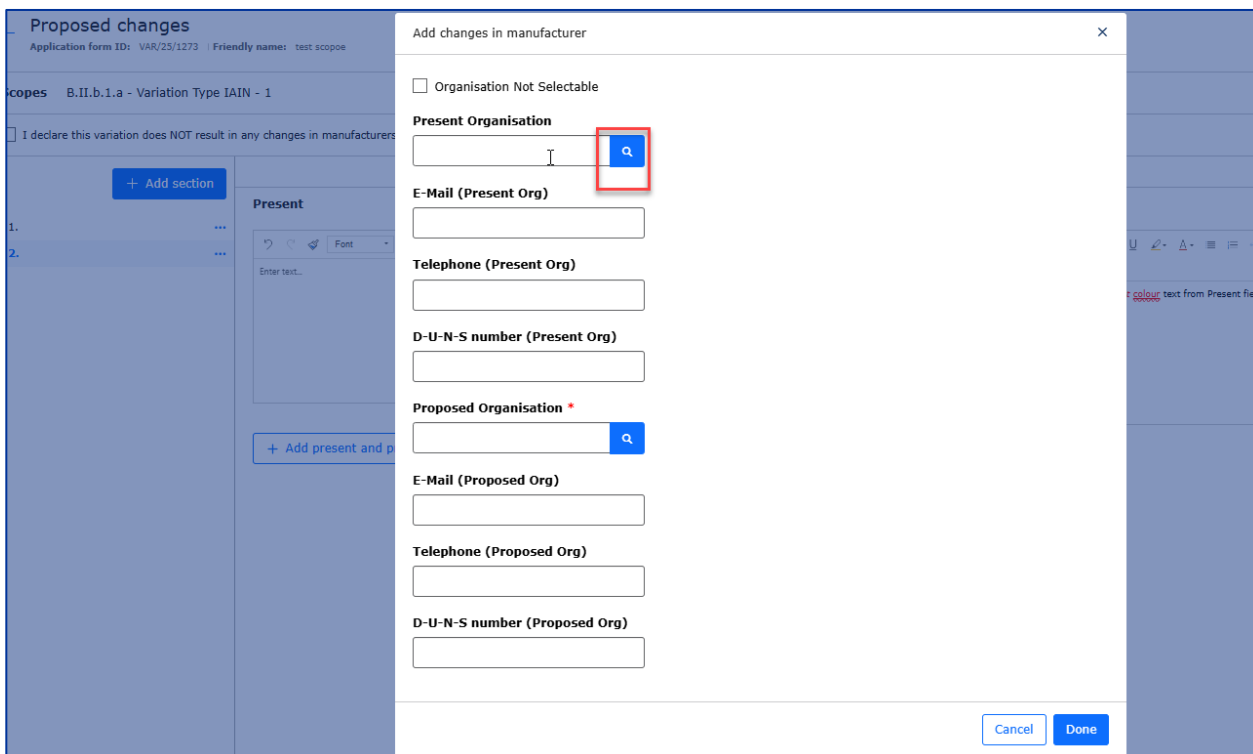
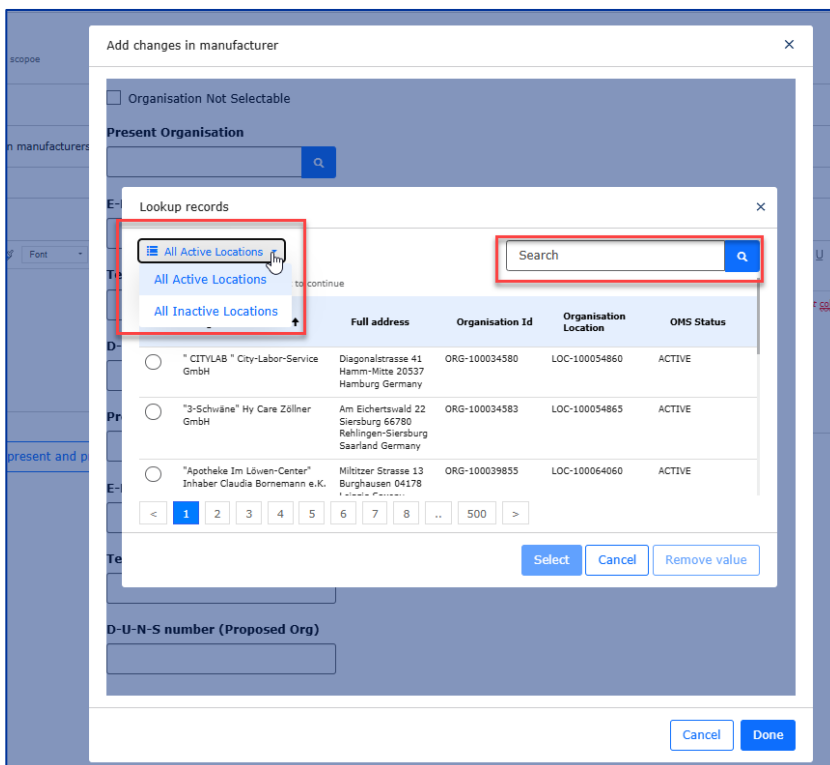


Figure 86 - Proposed Changes - Add/Edit Organisation

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



Organisation Not Selectable

Present Organisation

Lookup records

All Active Locations

All Active Locations

All Inactive Locations

	Full address	Organisation Id	Organisation Location	OMS Status
<input type="radio"/>	"CITYLAB" City-Labor-Service GmbH Diagonalstrasse 41 Hamm-Mitte 20537 Hamburg Germany	ORG-100034580	LOC-100054860	ACTIVE
<input type="radio"/>	"3-Schwane" Hy Care Zöllner GmbH Am Eichertsvald 22 Siersburg 66780 Rellingem-Siersburg Saarland Germany	ORG-100034583	LOC-100054865	ACTIVE
<input type="radio"/>	"Apotheke Im Löwen-Center" Inhaber Claudia Bornemann e.K. Militzer Strasse 13 Burghausen 04178 Thüringen Germany	ORG-100039855	LOC-100064060	ACTIVE

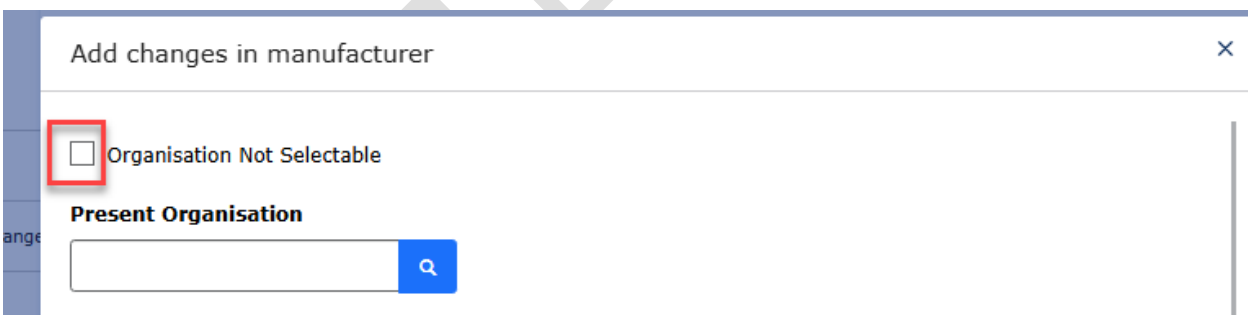
Select Cancel Remove value

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

Cancel Done

Figure 87 - Select Present Organisation

- 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.



Add changes in manufacturer

☒ Organisation Not Selectable

Present Organisation

Figure 88 - Organisation Not Selectable

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

County

Country *

E-Mail (Present Org)

Telephone (Present Org)

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

Proposed Organisation *

Figure 89 - Data of Not Selectable Organisation

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

Add changes in manufacturer

☐ Organisation Not Selectable

Present Organisation

E-Mail (Present Org)

Telephone (Present Org)

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

Proposed Organisation *

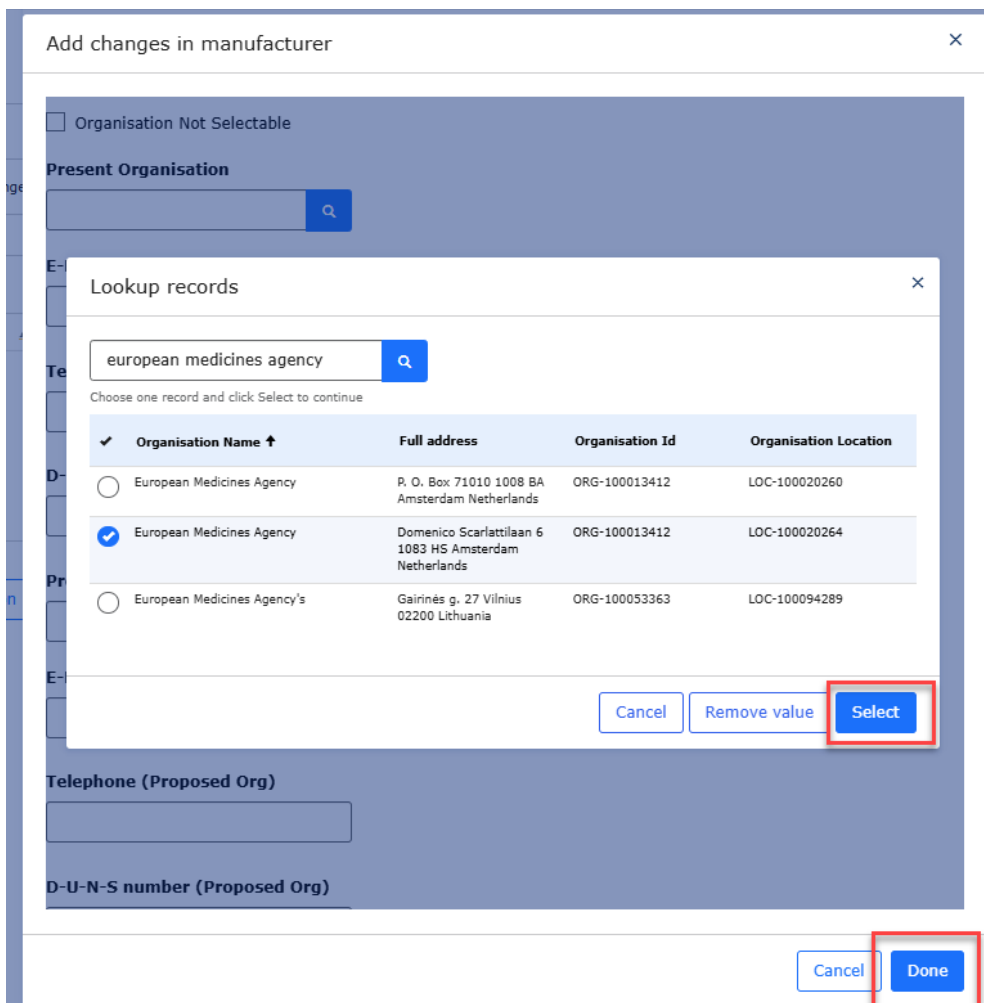
E-Mail (Proposed Org)

Telephone (Proposed Org)

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

Figure 90 - Proposed Organisation

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



Add changes in manufacturer

☐ Organisation Not Selectable

Present Organisation

Lookup records

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

Cancel Remove value **Select**

Telephone (Proposed Org)

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

Cancel **Done**

Figure 91 - Present and Proposed Section

- 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.

☐ 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

Proposed

Enter text...

Present Organisation

Organisation Name	European Medicines Agency
Organisation Location	LOC-100020260
Organisation ID	ORG-100013412
Address	P. O. Box 71010 1008 BA Amsterdam Netherlands
Parent organisation	European Medicines Agency
Modified on	2024-11-20T10:41:09Z
Email address	
Telephone number	
D-U-N-S number	

Proposed Organisation

Organisation Name	European Medicines Agency
Organisation Location	LOC-100020264
Organisation ID	ORG-100013412
Address	Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands
Parent organisation	European Medicines Agency
Modified on	2025-01-14T16:27:02Z
Email address	
Telephone number	
D-U-N-S number	

+ Add present and proposed organisation

Figure 92 - Present and Proposed Value(s)

2.5.3. Add Package to an Existing Product

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

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

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

Figure 93 – Edit & Add Package

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

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"/>	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

Figure 94 - Add Package

Figure 95 - Add Package Details

- 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 *

MA Number *

Pack Size *

Figure 96 - Parent Medicinal Product Selection

Add package x

Parent Medicinal Product *

MA Number * **Pack Size ***

Lookup records x

Choose one record and click 'Select' to continue

Product Name *	MRP / CP Number	MA Number	Authorisation Country	PHS ID
<input checked="" type="radio"/> Zejula 100 mg film-coated tablets	EMA/H/C/004249	EU/1/17/1235	European Union	
<input type="radio"/> Zejula 100 mg hard capsules	EMA/H/C/004249	EU/1/17/1235	European Union	

Cancel Remove value Select

Figure 97 - Parent Medicinal Product Selection

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

Add package x

Parent Medicinal Product *

Zejula 100 mg film-coated tablets

MA Number * **Pack Size ***

EU/1/17/1235/008

100 tablets

Done

Figure 98 - Add Package Submission

11. You can now see the newly added pack size in the list of packaged medicinal products.
12. As the existing package is auto selected, it is important to untick the existing pack size (shown with the green arrow). As the change is to add the new pack size, we need to remove the existing pack size from the scope of this change.

Edit selected
×

Product packages
Scope

Add Package

<input type="checkbox"/>	MA Number	MRP/CP Number	Package ID	Package size	Authorisation status	Pack description
<input type="checkbox"/>	Zejula 100 mg hard capsules, 600000000423					
<input type="checkbox"/>	EU/1/17/1235/001	EMEA/H/C/004249	76863	84 x 1 capsules (unit dose)	Valid - Transferred marketing authorisation	Packaging: blister (PCTFE/PVC/alu), Package size: 84 x 1 capsules (unit dose)
<input type="checkbox"/>	EU/1/17/1235/002	EMEA/H/C/004249	76864	56 x 1 capsules (unit dose)	Valid	Packaging: blister (PCTFE/PVC/alu), Package size: 56 x 1 capsules (unit dose)
<input type="checkbox"/>	EU/1/17/1235/003	EMEA/H/C/004249	76865	28 x 1 capsules (unit dose)	Valid	Packaging: blister (PCTFE/PVC/alu), Package size: 28 x 1 capsules (unit dose)
<input checked="" type="checkbox"/>	Zejula 100 mg film-coated tablets, 600000094947					
<input checked="" type="checkbox"/>	EU/1/17/1235/008	EMEA/H/C/004249		100 tablets	Pending	ⓘ
<input type="checkbox"/>	EU/1/17/1235/005	EMEA/H/C/004249	7940002	84 tablets	Valid	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic), Package size: 84 tablets
<input type="checkbox"/>	EU/1/17/1235/004	EMEA/H/C/004249	7940003	56 tablets	Valid	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic), Package size: 56 tablets
<input type="checkbox"/>	EU/1/17/1235/006	EMEA/H/C/004249	26500019	56 tablets	Valid	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic/paper), Package size: 56 tablets
<input type="checkbox"/>	EU/1/17/1235/007	EMEA/H/C/004249	26500020	84 tablets	Valid	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic/paper), Package size: 84 tablets

Cancel
Done

Figure 99 - Unticking the Existing Pack Size

13. Proceed to save the change.

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

Product selection
Products concerned by this application ⓘ

Column visibility ▾
Associate MRP Nr.
Q Search
+ Select products

Full name	Authorised dose form	Active substance	Authorisation country	MA holder	MA no.	MRP / CP no.	PHS ID	MP ID	Authorisation status	MRP variation no.	No. of selected packages
Zejula 100 mg film-coated tablets	Film-coated tablet	Niraparib, Niraparib tosilate monohydrate	European Union	Glaxosmithkline (Ireland) Limited	EU/1/17/1235	EMEA/H/C/004249	600000094947		Valid		1/5

Selected packaged medicinal products

MA number	Package size	Package ID	Package description	Authorisation status
<input checked="" type="checkbox"/> EU/1/17/1235/008	100 tablets			Pending
<input type="checkbox"/> EU/1/17/1235/005	84 tablets	7940002	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic), Package size: 84 tablets	Valid
<input type="checkbox"/> EU/1/17/1235/004	56 tablets	7940003	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic), Package size: 56 tablets	Valid
<input type="checkbox"/> EU/1/17/1235/006	56 tablets	26500019	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic/paper), Package size: 56 tablets	Valid
<input type="checkbox"/> EU/1/17/1235/007	84 tablets	26500020	Packaging: blister (OPA/alu/PVC/alu/vinyl/acrylic/paper), Package size: 84 tablets	Valid

Zejula 100 mg hard capsules	Capsule, hard	Niraparib tosilate monohydrate	European Union	Glaxosmithkline (Ireland) Limited	EU/1/17/1235	EMEA/H/C/004249	600000000423		Valid		3/3
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Figure 100 - Pending Entry

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

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

2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

Active Substance			
Oc...log alfa			
MA Number(s) ⁸	Full name ²¹	MA Holder name	Member state Pharmaceutical Form ²²
EU/1/1.../0XX	K... solvent for solution for		European Union Powder and solvent for solution for injection
EU/1/1.../0XY	K... solvent for solution for injection		European Union Powder and solvent for solution for injection

Figure 101 - Products Concerned by the Application

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

Scope	B.II.e.5.a.1 - Variation Type IAIN - 1	
Product(s) Package(s)	K... 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) <i>Add details to present and proposed fields as per normal</i>
	Present ^{9,10}	Proposed ^{9,10}
	EU/1/1.../76/0XX	
	Package - MA number: EU/1/1.../76/0XX - Description: 1 + 1 (new multipack)	<i>These fields contain the information from the MA number and Pack size fields in the pop up window</i>
<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		

Figure 102 - Information Summary

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

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

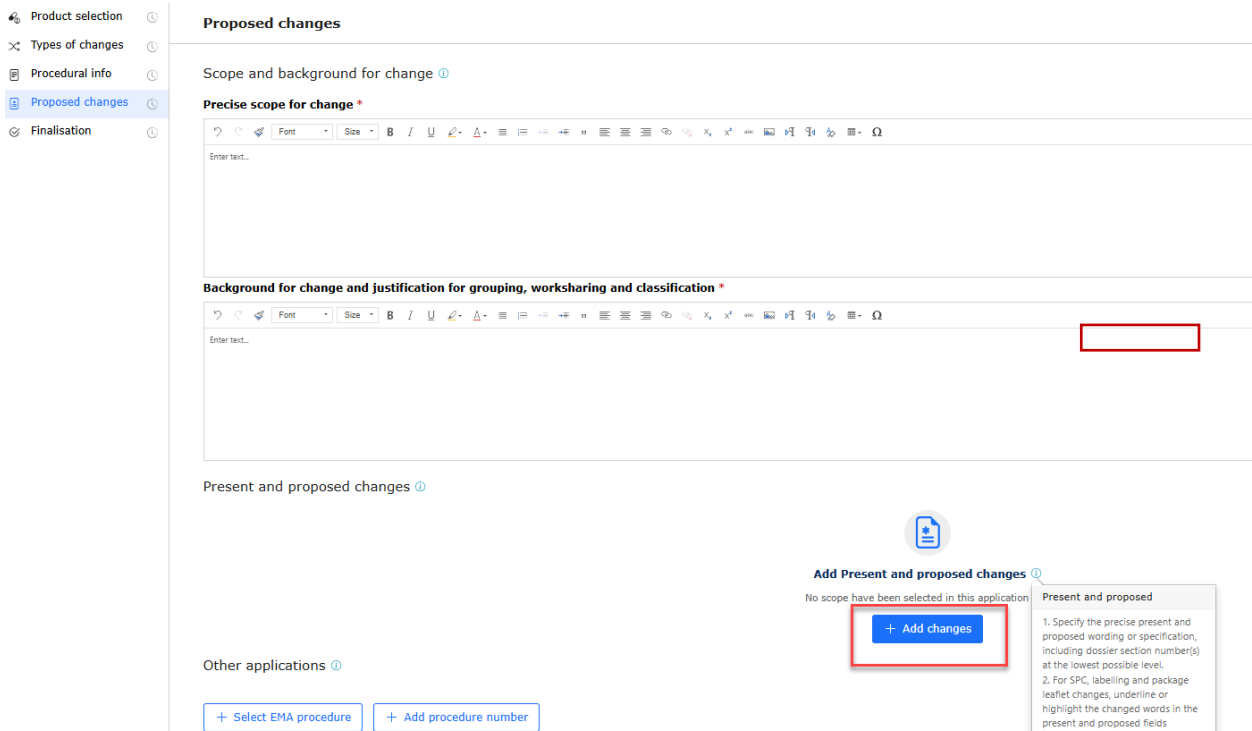


Figure 103 - Add Present and Proposed

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

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

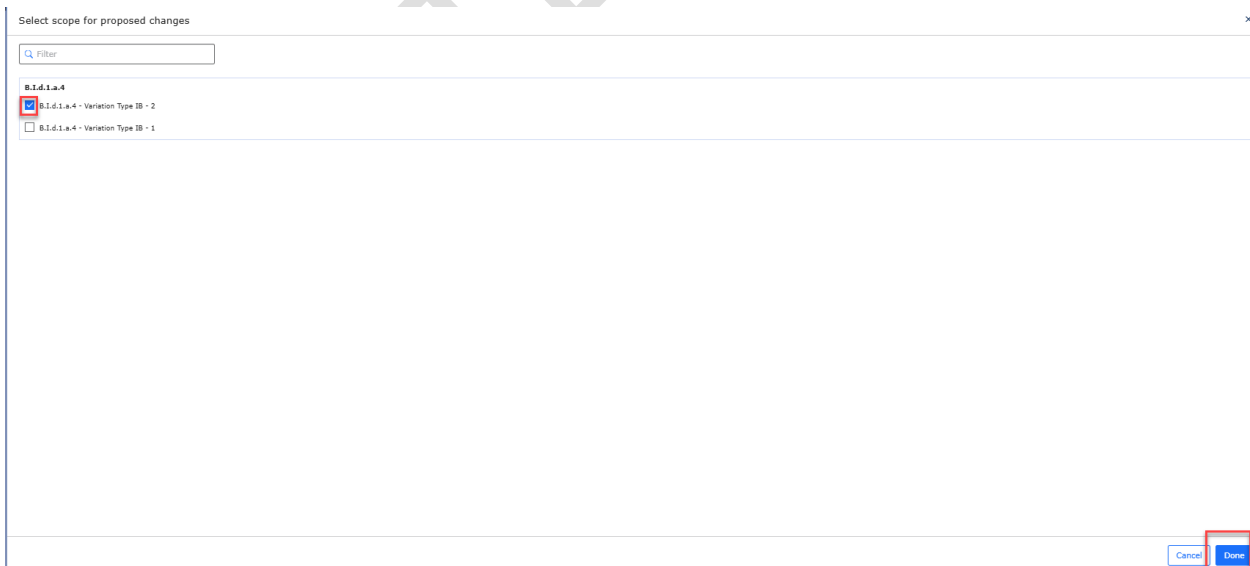
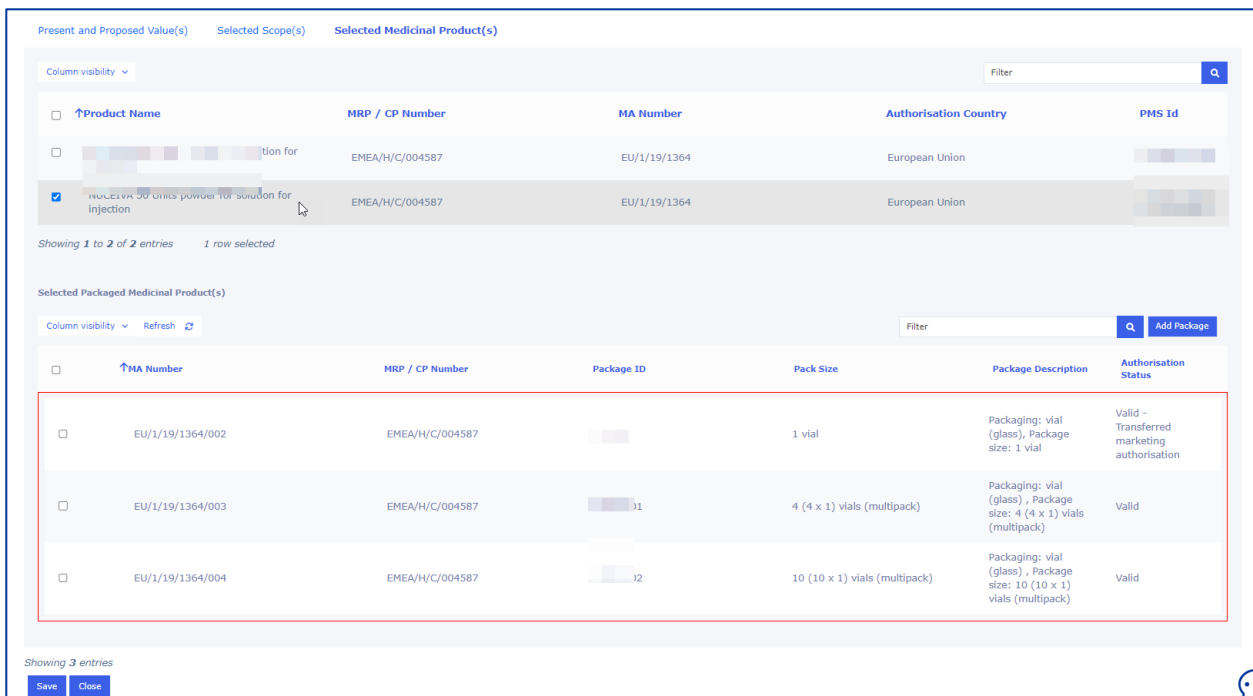


Figure 104 - Scope Selection

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

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



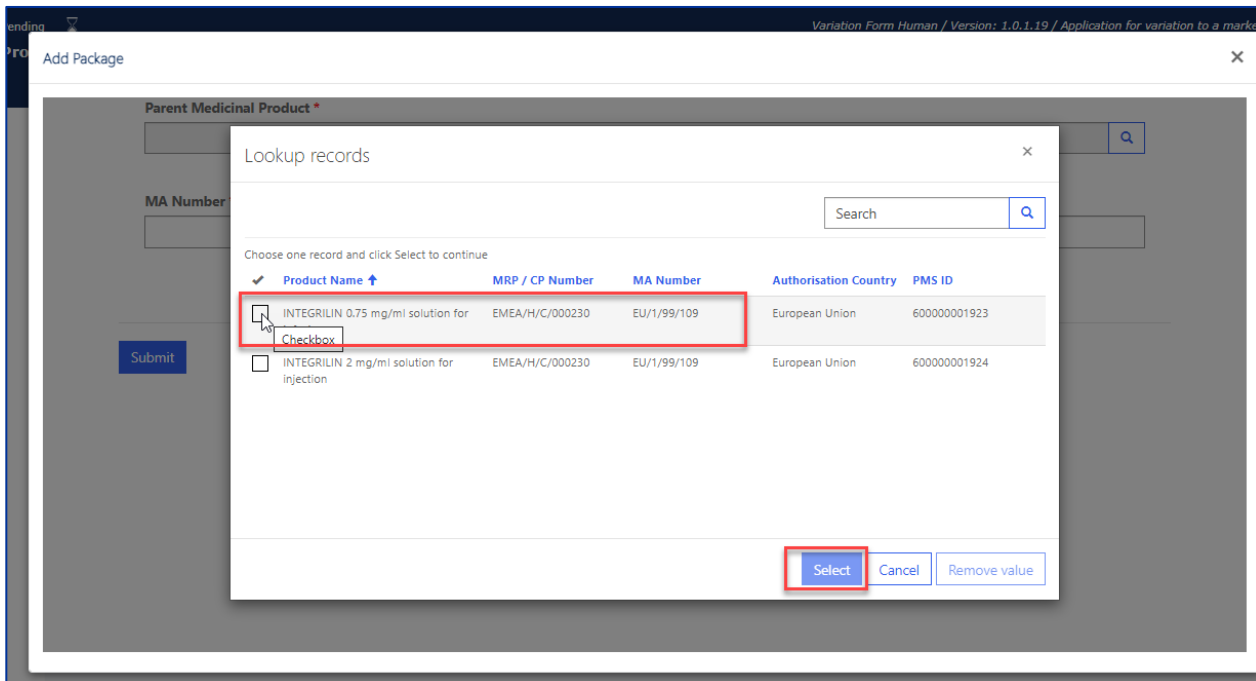
The screenshot shows a pop-up window with two main sections. The top section, 'Selected Medicinal Product(s)', contains a table with columns: Product Name, MRP / CP Number, MA Number, Authorisation Country, and PMS Id. Two rows are visible, both for 'PROLEVA 500 ORIS powder for solution for injection' with MA Number EU/1/19/1364 and Authorisation Country European Union. The bottom section, 'Selected Packaged Medicinal Product(s)', contains a table with columns: MA Number, MRP / CP Number, Package ID, Pack Size, Package Description, and Authorisation Status. Three rows are visible, all for MA Number EU/1/19/1364 and MRP / CP Number EMEA/H/C/004587. The first row has Package ID 001, Pack Size 1 vial, and Authorisation Status Valid - Transferred marketing authorisation. The second row has Package ID 002, Pack Size 4 (4 x 1) vials (multipack), and Authorisation Status Valid. The third row has Package ID 003, Pack Size 10 (10 x 1) vials (multipack), and Authorisation Status Valid. A red box highlights the bottom section. At the bottom of the window are 'Save' and 'Close' buttons.

Product Name	MRP / CP Number	MA Number	Authorisation Country	PMS Id
PROLEVA 500 ORIS powder for solution for injection	EMEA/H/C/004587	EU/1/19/1364	European Union	
PROLEVA 500 ORIS powder for solution for injection	EMEA/H/C/004587	EU/1/19/1364	European Union	

MA Number	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status
EU/1/19/1364/002	EMEA/H/C/004587	001	1 vial	Packaging: vial (glass), Package size: 1 vial	Valid - Transferred marketing authorisation
EU/1/19/1364/003	EMEA/H/C/004587	002	4 (4 x 1) vials (multipack)	Packaging: vial (glass), Package size: 4 (4 x 1) vials (multipack)	Valid
EU/1/19/1364/004	EMEA/H/C/004587	003	10 (10 x 1) vials (multipack)	Packaging: vial (glass), Package size: 10 (10 x 1) vials (multipack)	Valid

Figure 105 - Pop-up Window

- Click the option "add package", this will open a pop up window to select the parent medicinal product and to include the details for the new pack size
- 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.
- Type the 'proposed' MA number for the new pack size in the MA number field, in some cases, it is possible that you could 'guess' which one the new presentation will be given, alternatively, you can simply enter 'to be confirmed' or the root MA number into the field for example: EU/1/123/1234/00X.
- Enter the pack size details in the pack size field and click 'Submit' button.



Lookup records

Choose one record and click Select to continue

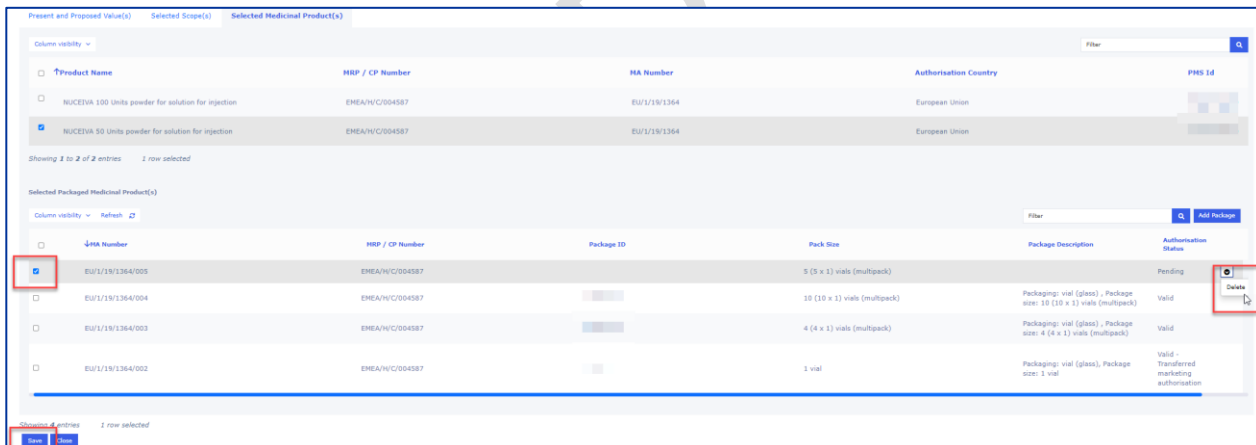
Product Name	MRP / CP Number	MA Number	Authorisation Country	PMS ID
INTEGRILIN 0.75 mg/ml solution for	EMEA/H/C/000230	EU/1/99/109	European Union	600000001923
INTEGRILIN 2 mg/ml solution for injection	EMEA/H/C/000230	EU/1/99/109	European Union	600000001924

Select Cancel Remove value

Figure 106 - Lookup Records

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

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



Selected Medicinal Product(s)

Product Name	MRP / CP Number	MA Number	Authorisation Country	PMS ID
NUCEIVA 100 Units powder for solution for injection	EMEA/H/C/004587	EU/1/19/1364	European Union	
NUCEIVA 50 Units powder for solution for injection	EMEA/H/C/004587	EU/1/19/1364	European Union	

Showing 1 to 2 of 2 entries 1 row selected

Selected Packaged Medicinal Product(s)

MA Number	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status
EU/1/19/1364/005	EMEA/H/C/004587		5 (5 x 1) vials (multipack)		Pending
EU/1/19/1364/004	EMEA/H/C/004587		10 (10 x 1) vials (multipack)	Packaging: vial (glass), Package size: 10 (10 x 1) vials (multipack)	Valid
EU/1/19/1364/003	EMEA/H/C/004587		4 (4 x 1) vials (multipack)	Packaging: vial (glass), Package size: 4 (4 x 1) vials (multipack)	Valid
EU/1/19/1364/002	EMEA/H/C/004587		1 vial	Packaging: vial (glass), Package size: 1 vial	Valid - Transferred marketing authorisation

Showing 1 to 4 of 4 entries 1 row selected

Delete

Figure 107 - Save Draft Package

28. Proceed to save the change.

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

Present and Proposed Value(s)			
Selected Scope(s)		Selected Medicinal Product(s)	
Column visibility	Identifier	Scope	Recommended Change(s)
<input type="checkbox"/>	B.II.a.5.a.1 - Variation Type IADN - 1	B.II.a.5.a.1 Change within the range of the currently approved pack sizes	Text / Org. Changes
<input checked="" type="checkbox"/>	B.II.a.5.a.1 - Variation Type IADN - 2	B.II.a.5.a.1 Change within the range of the currently approved pack sizes	Text / Org. Changes
<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	Pharmaceutical Group (ATC)
Description			
S.II.a.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			
S.II.a.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			
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			

Showing 1 to 3 of 3 entries 1 row selected

[View](#) [Close](#)

Figure 108 - Select Scope

Add Package

Parent Medicinal Product *
NUCEVA 100 Units powder for solution for injection

MA Number *
EU/1/19/1364/006

Pack Size *
2 x 1 vial (multipack)

[Submit](#)

Showing 1 to 2 of 2 entries 1 row selected

Trn Number	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status
EU/1/20/1364/001	EMA/N/20/4387	58541	1 vial	Packaging: vial (glass), Package size: 1 vial	Valid - Transferred marketing authorisation

Showing 1 entries 1 row selected

[View](#) [Close](#)

Figure 109 - Add Package Submission

Product Selection

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
Carvykti 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)

Full Name	Pack Size	Package Description	MA Number	Package ID	Authorisation Status
Carvykti 3.2 x 10^6 - 1 x 10^8 cells dispersion for infusion	1 bag	Packaging: 30 ml of 70 ml	EU/1/22/1648/001		Valid
Carvykti 3.2 x 10^6 - 1 x 10^8 cells dispersion for infusion	1 bag (content 15 ml)		EU/1/22/1648/002		Pending

Figure 110 - Pending Submission

- 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				
Oc...log alfa				
MA Number(s) ⁸	Full name ²¹	MA Holder name	Member state	Pharmaceutical Form ²²
EU/1/1.../0XX	K... solvent for solution for		European Union	Powder and solvent for solution for injection
EU/1/1.../0XY	K... solvent for solution for injection		European Union	Powder and solvent for solution for injection

Figure 111 - Products Concerned by the Application

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

Scope	B.II.e.5.a.1 - Variation Type IAIN - 1	
Product(s) Package(s)	K... 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) <i>Add details to present and proposed fields as per normal</i>
	Present ^{9,10}	Proposed ^{9,10}
	EU/1/1.../76/0XX	
	Package - MA number: EU/1/1.../76/0XX - Description: 1 + 1 (new multipack)	<i>These fields contain the information from the MA number and Pack size fields in the pop up window</i>
<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		

Figure 112 - Information Summary

2.5.3.3. Multiple change

Duplicating the Present and Proposed Fields

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

Linking of the organisations to the text changes

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

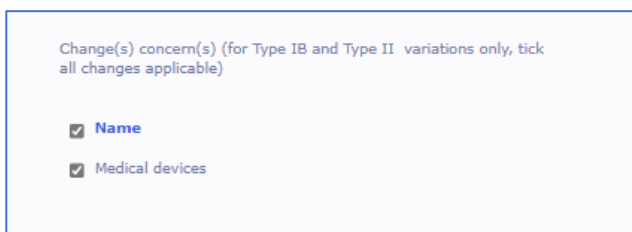
2.5.3.4. Structured changes

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

2.5.3.4. Medical Device(s)

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

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



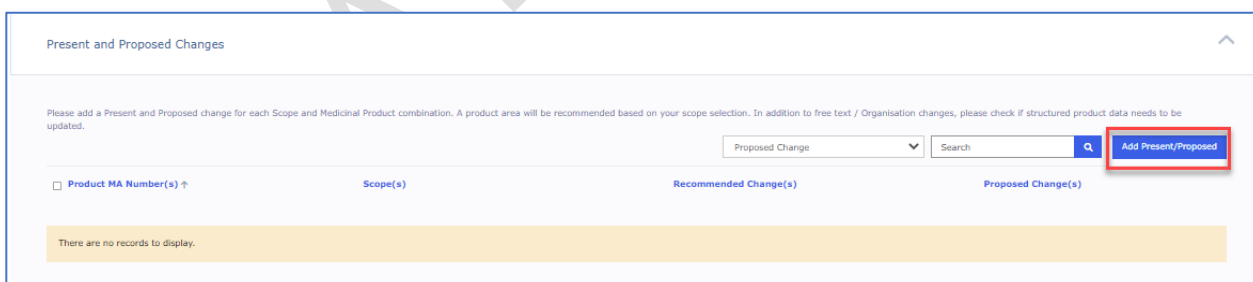
Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

☒ Name

☒ Medical devices

Figure 113 - Medical Device Box

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



Present and Proposed Changes

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

Proposed Change ▼ Search 🔍 **Add Present/Proposed**

Product MA Number(s) ↑	Scope(s)	Recommended Change(s)	Proposed Change(s)
There are no records to display.			

Figure 114 - Add Present/Proposed Changes

3. Select the scope and the medicinal product/presentations

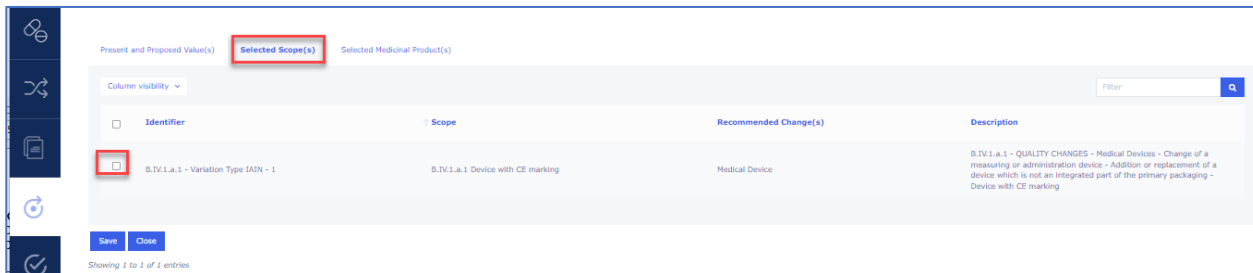


Figure 115 - Selected Scope(s)

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

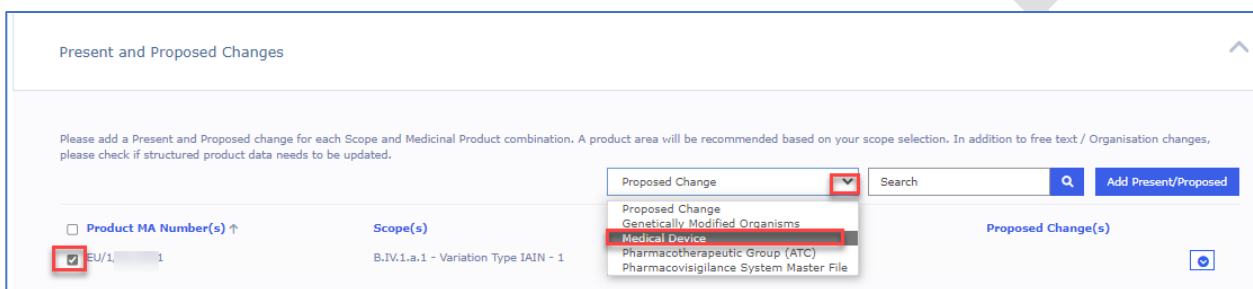


Figure 116 - Selection of Relevant Scope/Product Combination

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

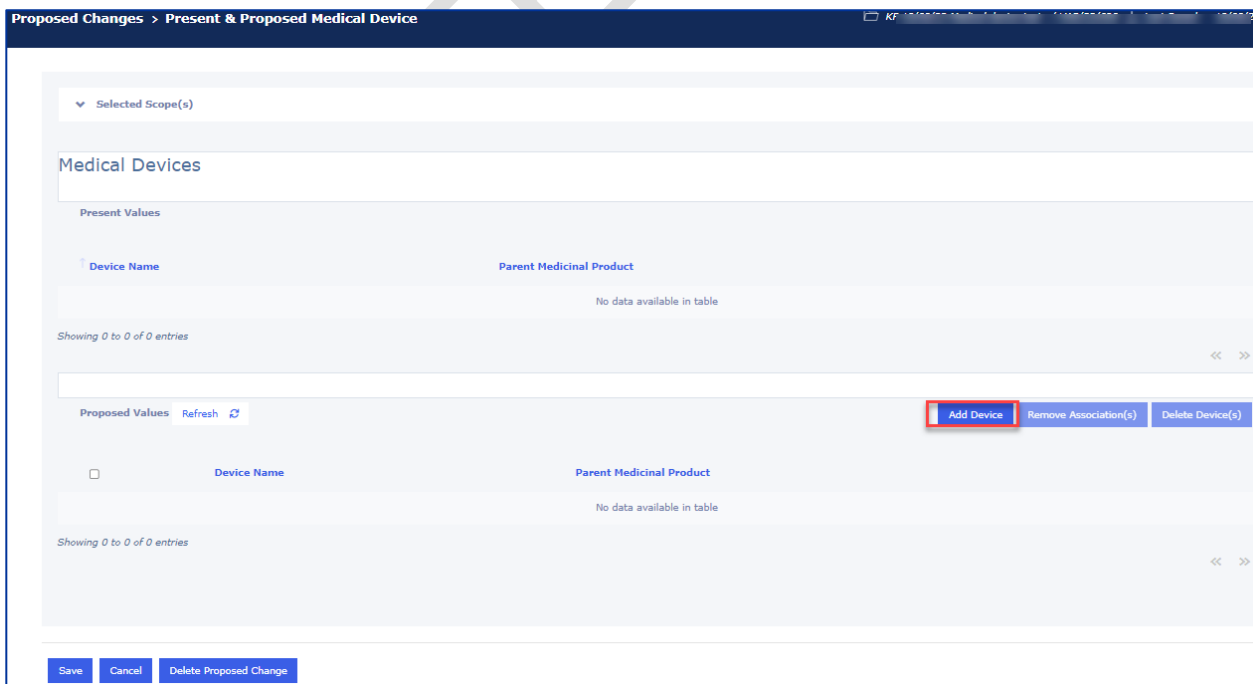


Figure 117 - Add Device

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



Medical Device & Companion Diagnostic

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

Save Cancel

Figure 118 - Medical Device and Companion Diagnostic

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



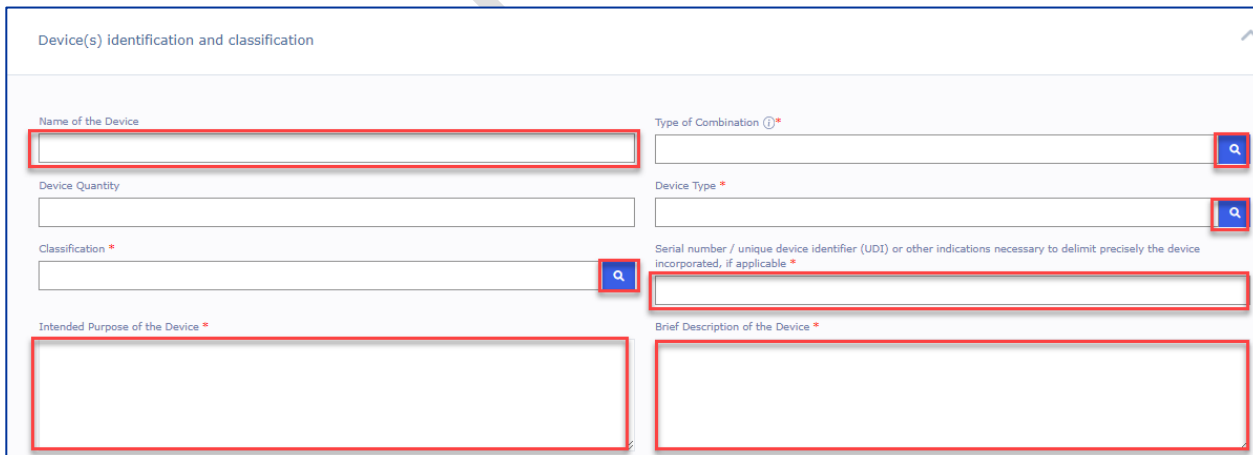
Medical Device & Companion Diagnostic

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

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

Figure 119 - Change Selection - Medical Device and Companion Diagnostic

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



Device(s) identification and classification

Name of the Device

Type of Combination (i) *

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 *

Figure 120 - Device(s) Identification and Classification

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

Manufacturer of the device

Function *

Manufacturer *

Title *

First Name *

Last Name *

Telephone

E-Mail

Figure 121 - Manufacturer of the Device

10. Proceed to fill in the rest of the sections

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

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

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

Figure 122 - Upload of Documentation

11. Notified body is also now selected from OMS

Notified Body (NB)

Notified Body Number *

Name of the Notified Body *

Title *

First Name *

Last Name *

Telephone

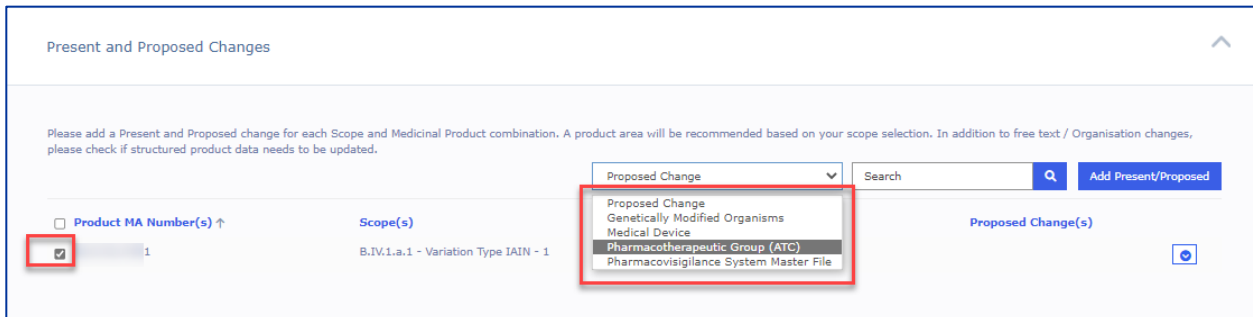
E-Mail

Figure 123 - Notified Body

2.5.3.5. ATC Code change

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

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



Present and Proposed Changes

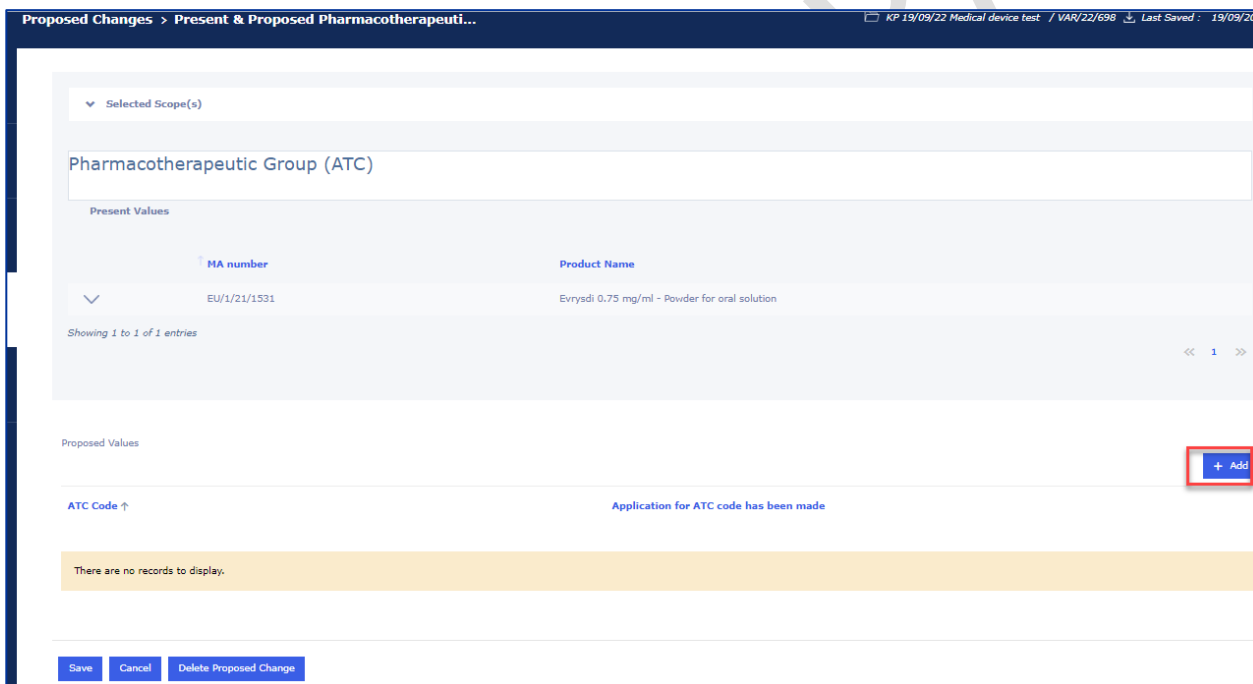
Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based on your scope selection. In addition to free text / Organisation changes, please check if structured product data needs to be updated.

☐ Product MA Number(s) ↑ Scope(s) B.IV.1.a.1 - Variation Type IAIN - 1 Proposed Change Search Add Present/Proposed

☒ 1 Proposed Change Proposed Change Genetically Modified Organisms Medical Device Pharmacotherapeutic Group (ATC) Pharmacovigilance System Master File Proposed Change(s) + Add

Figure 124 - Present and Proposed Changes

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



Proposed Changes > Present & Proposed Pharmacotherapeuti... KP 19/09/22 Medical device test / VAR/22/698 Last Saved : 19/09/202

Selected Scope(s)

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 << 1 >>

Proposed Values

ATC Code ↑ Application for ATC code has been made + Add

There are no records to display.

Save Cancel Delete Proposed Change

Figure 125 - ACT Code Change

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

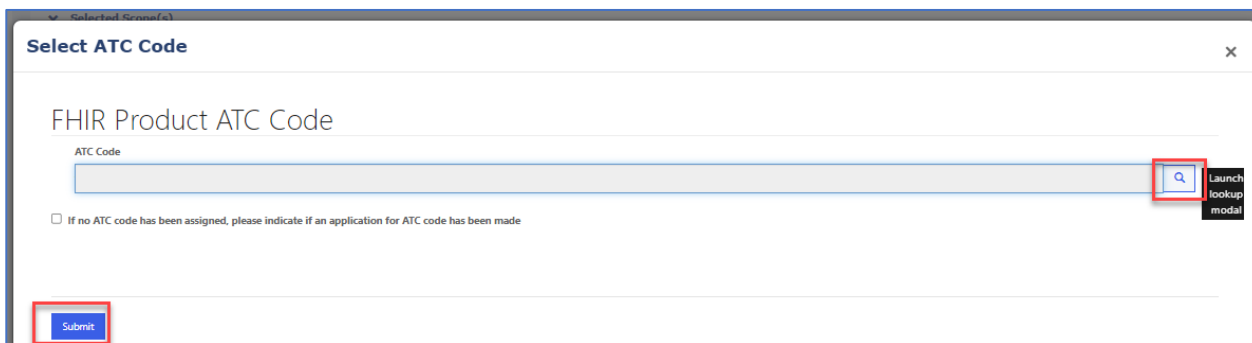


Figure 126 - Selection of ATC Code

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

2.5.3.6. Pharmacovigilance System Master File

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

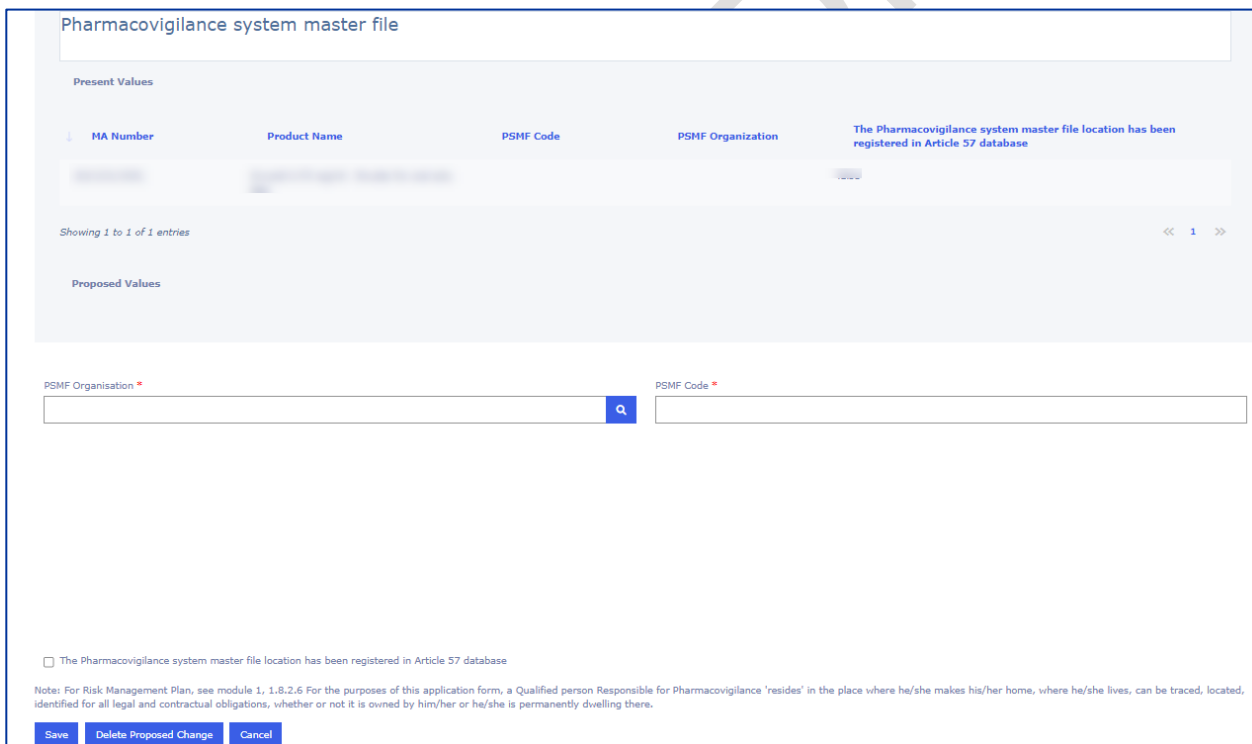

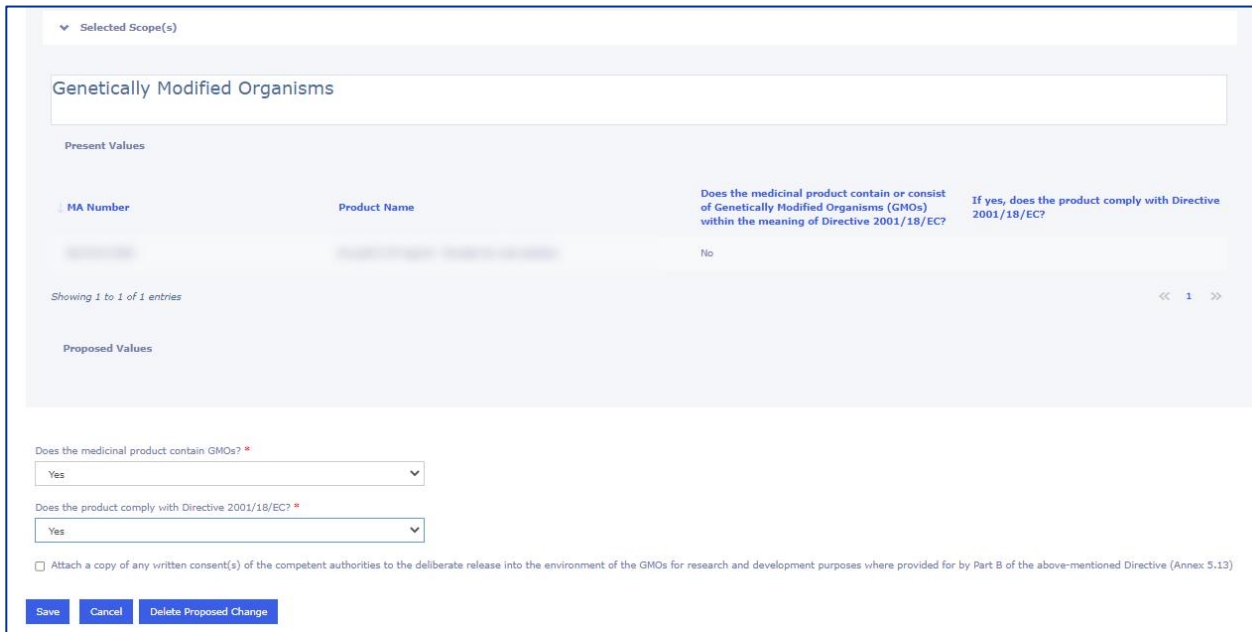


Figure 127 - Pharmacovigilance System Master File

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

2.5.3.7. Genetically Modified Organisms

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



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

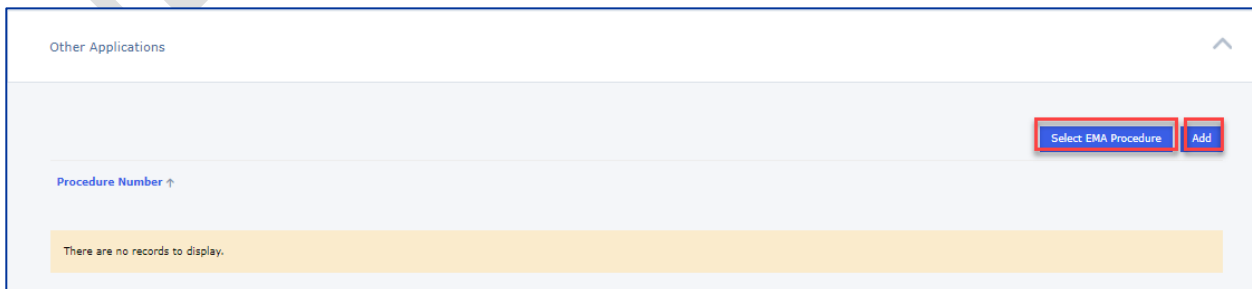
Figure 128 - Genetically Modified Organisms Code

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

2.5.3.4. Other applications

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

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



Other Applications

Select EMA Procedure Add

Procedure Number ↑

There are no records to display.

Figure 129 - Selection of EMA Procedure

2.6. Additional Information

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



Figure 130 - Additional Information Section

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

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

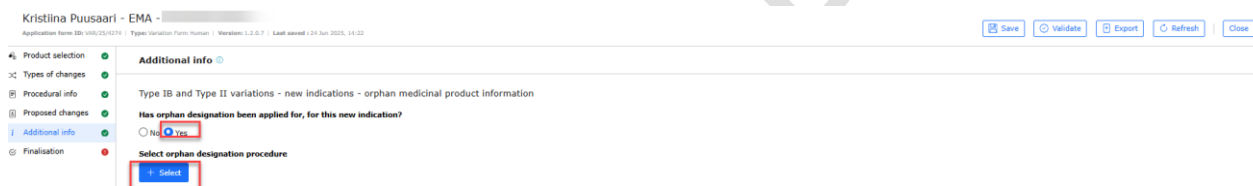
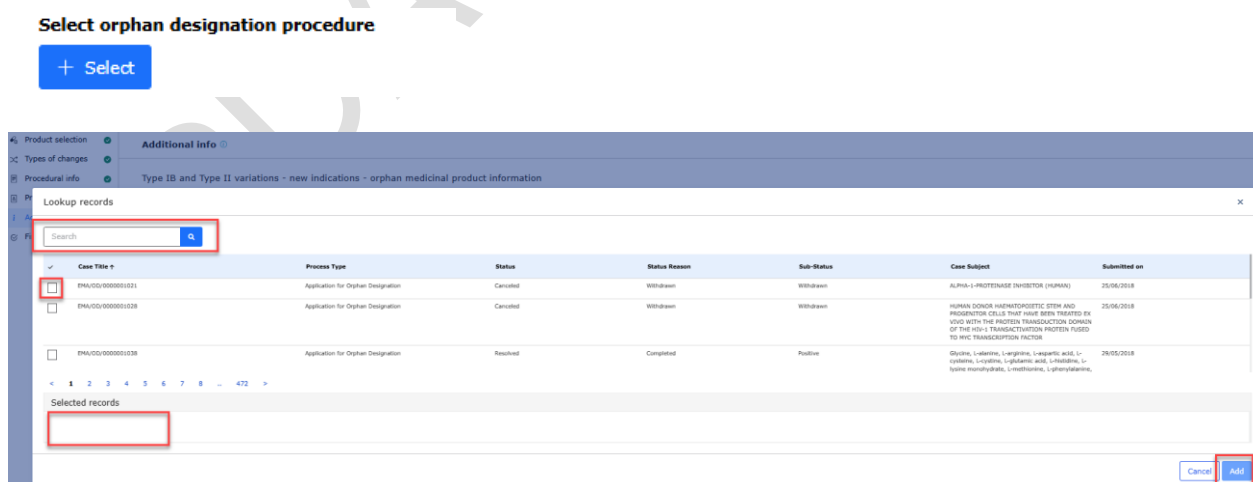


Figure 131 - Orphan Designation Procedure

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



Case Title	Process Type	Status	Status Reason	Sub-Status	Case Subject	Submitted on
EMA/CO/000001021	Application for Orphan Designation	Cancelled	Withdrawn	Withdrawn	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	25/06/2018
EMA/CO/000001028	Application for Orphan Designation	Cancelled	Withdrawn	Withdrawn	HUMAN DONOR HEMATOPOIETIC STEM AND PROGENITOR CELLS THAT HAVE BEEN TREATED IN VIVO WITH THE PROTEIN TRANSDUCTION DOMAIN OF THE HIV-1 TRANSCRIPTION PROTEIN FUSED TO MYC TRANSCRIPTION FACTOR	25/06/2018
EMA/CO/000001038	Application for Orphan Designation	Resolved	Completed	Positive	Glycine, L-valerine, L-leucine, L-isopropyl acid, L-lysine, L-serine, L-glutamic acid, L-threonine, L-isoleucine, L-histidine, L-phenylalanine,	28/05/2018

Figure 132 - Lookup Records

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

Select orphan designation procedure

+ Select

Orphan designation procedure	Orphan designation procedure status	Orphan designation date	Commission decision reference number	Based on the criterion of "significant benefit"	Number in the Community Register of Orphan Medicinal Products	Copy of Designation Decision	Action
EMA/C/000000/2018	Orphan Designation Withdrawn				Yes		
EMA/C/000000/2019	Orphan Designation Granted	19/11/2019	1087	No	Yes		
EMA/C/000000/2020	Orphan Designation Granted	17/07/2020	1153	Yes	Yes		

Figure 133 - Selection of Procedure

2.6.2. Information relating to orphan market exclusivity

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

Information relating to orphan market exclusivity

Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the new indication proposed in this variation application?

☐ No ☒ Yes

EU orphan designation number(s) * 

+ Select

EU Orphan designation number	↓ Entitlement Type	Name of active substance(s) for Decision	Agreed scope	Agreed condition/indication	Action
EU [REDACTED]	Orphan Designation	[REDACTED]	Treatment of	[REDACTED] ophathy	Download
EU [REDACTED]	Orphan Designation	[REDACTED]	Treatment of	[REDACTED] loma	Download
EU [REDACTED]	Orphan Designation	[REDACTED] ation	Treatment of	[REDACTED] loma	Download
EU [REDACTED]	Orphan Designation	[REDACTED]	Treatment of	[REDACTED] loma	Download

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

Has any of the designated Orphan medicinal product(s) been granted a marketing authorization in the EU?

☐ No ☒ Yes

Specify for authorised product: * ⓘ

+ Select

Specify for authorised product:

Please select the relevant authorised orphan medicinal product

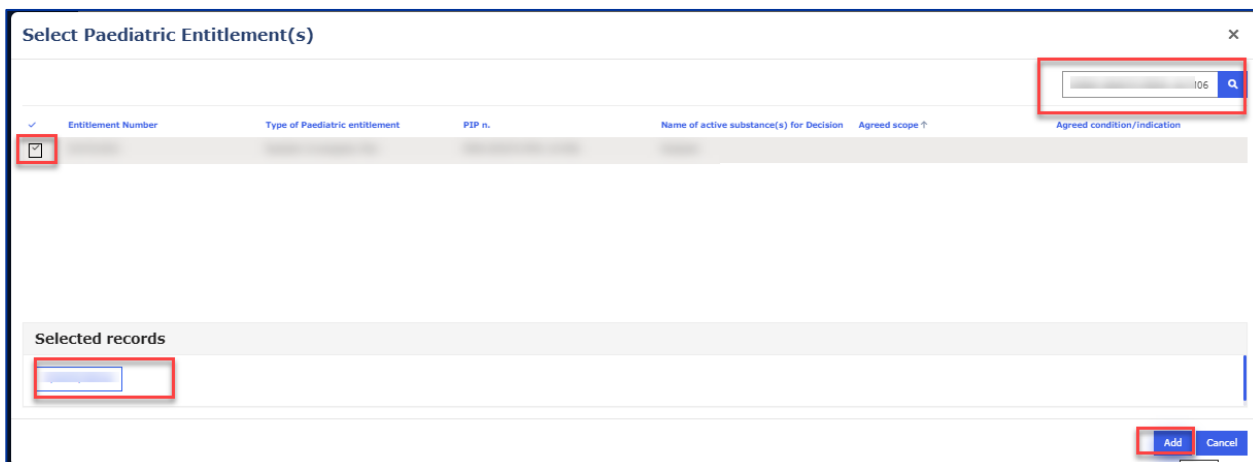


Figure 136 - Addition of Paediatric Entitlement(s)

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



Figure 137 - Recap Table of Paediatric Entitlement(s)

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

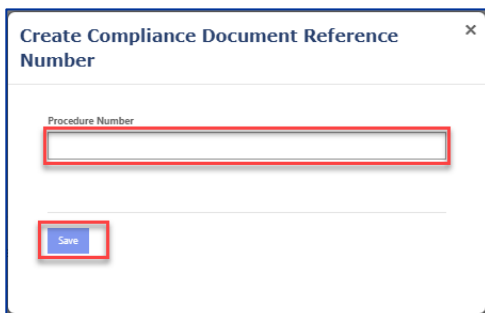


Figure 138 - Creation of Compliance Document Reference Number

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



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

2.7. Finalisation section

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

Kristiina Puusaari - EMA - Prod test check ...

Application form 32b V40/22/4274 | Types notification Form Human | Version: 1.2.0.7 | Last saved: 22 Jun 2025, 13:48

Save Validate Export Refresh Finalise Close

Finalisation

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.

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

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)

- ☐ For type IA notifications: the required documents as specified for the changes concerned have been submitted;
- ☐ 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, national fees have been prepaid or will be paid in accordance with national requirements;
- ☐ 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;
- ☐ 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:

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

- ☐ The applicant confirms that the same variation (or group of variations) does not apply to any other marketing authorisation held by the same holder (only applicable for Type IB and/or Type II variations).

Note:

Information on harmonisation of product information for MRP/DCP/purely nationally authorised products

1) Has/have the concerned MA(s) been harmonised or partially harmonised, by an Article 30 or 31(1) referral?

☒ No ☐ Yes

Procedure(s):

2) Has harmonisation of a section/some sections of the SmPC/PL/labeling been achieved through a variation worksharing?

☒ No ☐ Yes

Procedure(s):

Proof of payment

☒ All relevant fees have been prepaid to competent authorities.

☐ No relevant fees have been prepaid to competent authorities.

Signatories

Main signatory

First Name:

Surname:

Status(Job Title):

Date:

Additional signatory

First Name:

Surname:

Status(Job Title):

Date:

☐ 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 3.4.3 in Part 3A/Module 1 Application Form for each of the MAs concerned.

Figure 140 - Finalisation Process

2.7.1. Annexed documents (where appropriate)

Finalisation

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.

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

Figure 141 - Annexed Documents

2.7.2. Declaration of the applicant

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

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)

- ☐ The individuals whose data is included consented to its sharing with EMA and its further sharing by EMA with third parties such as other marketing authorisation applicants, marketing authorisation holders and National Competent Authorities, as relevant*
- ☐ For type IA notifications: the required documents as specified for the changes concerned have been submitted;
- ☐ All PIs (including annotated PIs are submitted in an anonymised format (i.e. names of the reviewers removed from the track-changes, no names in document properties and other parts of the documents)*
- ☐ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);*
- ☐ I understand that EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the marketing authorisation holder*
- ☐ For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.
- ☐ Where applicable, national fees have been prepaid or will be paid in accordance with national requirements;
- ☐ 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;
- ☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled;

Change(s) will be implemented from: *


<input type="checkbox"/> Next production run/next printing	
<div>Changes implementation date</div> <div>DD/MM/YYYY </div>	<div>Changes implementation comment</div> <div></div>

Figure 142 - Declaration of the Applicant

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

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

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

☐ The applicant confirms that the same variation (or group of variations) does not apply to any other marketing authorisation held by the same holder (only applicable for Type IB and/or Type II variations).

Note *

Figure 143 - Declaration of the Applicant

2.7.4 Proof of Payment

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

Proof of payment

☒ All relevant fees have been prepaid to competent authorities.

+ Add payment details

☐ No relevant fees have been prepaid to competent authorities.

+ Add payment details

Figure 144 - Proof of Payment

2.7.5 . Signatories

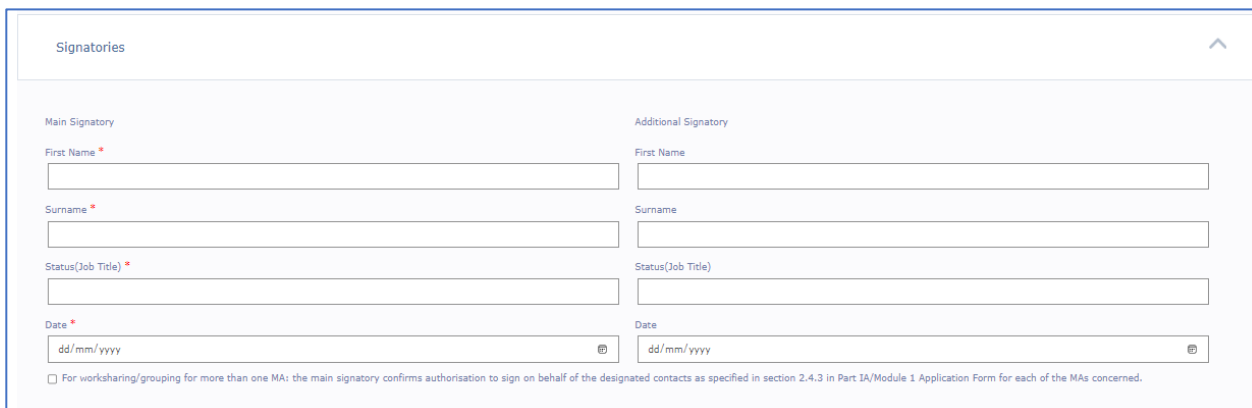


Figure 145 - Signatories

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

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

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

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

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

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

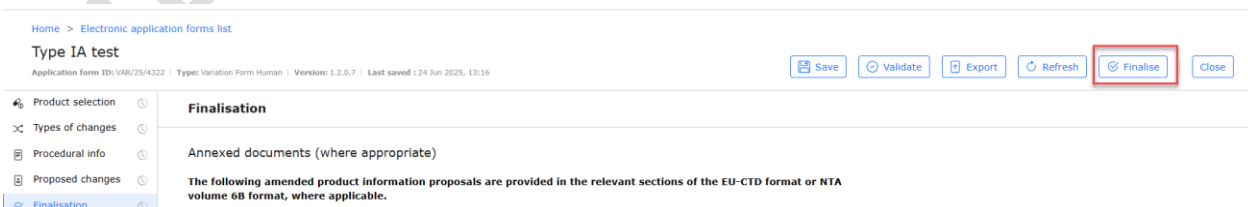


Figure 146 - Finalise Submission

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

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

UPDATED DRAFT

3. Exporting the form content to a PDF

3.2. PDF Export

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

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

Exports

Friendly name: VAR/25/4274 Application form ID: Kristiina Puusaari - EMA - Prod test ...

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

Active

Exports

Friendly name: VAR/25/4322 Application form ID: Type IA test

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

Application is ready to download.

Click the checkbox below to agree and download the application pdf file from the list

Completed

☐ I understand that the XML contained in the PDF will include commercially confidential information and product data from SPOR Product Management System (PMS).

Download

Export details

Modified on	Created on	Requestor	Status or reason	Validation XML	Export message	FHIR PDF
24/06/2025 15:48	24/06/2025 15:48	Kristiina Puusaari	Active			

Close

Figure 147 - Preparation of Export

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

Exports

×

Friendly name: VAR/25/4322 Application form ID: Type IA test

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

Application is ready to download.

☐ Click the checkbox below to agree and download the application pdf file from the list

Completed

☐ I understand that the XML contained in the PDF will include commercially confidential information and product data from SPOR Product Management System (PMS).

Download 

Export details

Column visibility 

Modified on	Created on	Requestor	Status or reason	Validation XML	Export message	FHIR PDF
24/06/2025 15:48	24/06/2025 15:48	Kristiina Puusaari	Active			

Close

Figure 148 - Export Completed

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

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


<input checked="" type="checkbox"/>		8329a58e-d235-ed11-a81b-000d3aae5...	18/09/2022 21:26	Adobe Acrobat D...	734 KB
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Figure 149 - Exported Form

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

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

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

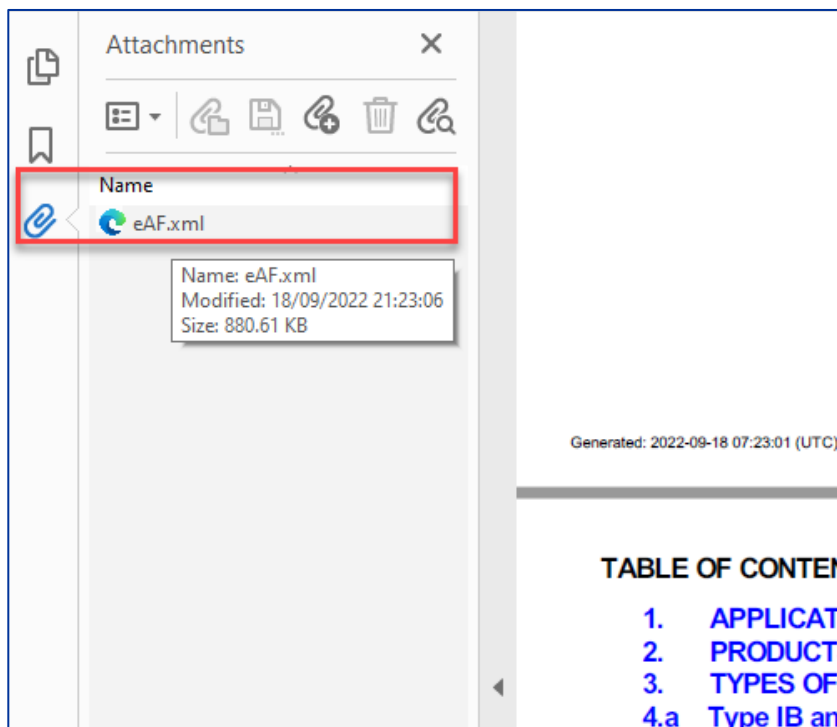


Figure 150 - FHIR xml

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

```

▼<Bundle xmlns="http://hl7.org/fhir">
  <id value="c683504d-41fa-4cf6-9de5-0fb249f77eaa"/>
  ▼<meta>
    <versionId value="V0.1"/>
  </meta>
  <type value="collection"/>
  ▼<entry>
    ▼<resource>
      ▼<Task>
        <id value="8329a58e3aae59e6f8d69a30ce653a8a"/>
        ▼<contained>
          ▼<List>
            <id value="taskProductList"/>
            <status value="current"/>
            <mode value="working"/>
            ▼<entry>
              ▼<item>
                <reference value="MedicinalProductDefinition/3de609f13aaa0711f8d69a30ce653a8a"/>
              </item>
            </entry>
          </List>
        </contained>
        ▼<contained>
          ▼<Task>
            <id value="variation-06abee533aaa0cebf8d69a30ce653a8a"/>
            ▼<identifier>
              <system value="http://ema.europa.eu/fhir/scopeIdentifier"/>
              <value value="C.I.6.a - Variation Type II - 1"/>
            </identifier>
            ▼<partOf>
              <reference value="#">
            </partOf>
            <status value="requested"/>
            <intent value="order"/>
            ▼<code>
              ▼<coding>
                <system value="https://spor.ema.europa.eu/v1/lists/100000152091"/>
                <code value="100000152602"/>
                <display value="C.I.6.a Addition of a new therapeutic indication or modification of an approved one"/>
              </coding>
              <text value="100000152602"/>
            </code>
            ▼<input>
              ▼<type>
                ▼<coding>
                  <system value="https://spor.ema.europa.eu/v1/lists/90000000001"/>
                  <code value="90000000004"/>
                  <display value="Not Applicable"/>
                </coding>
              </type>
              <valueBoolean value="false"/>
            </input>
          </Task>
        </contained>
      </resource>
    </entry>
  </Bundle>

```

Figure 151 - XML file - Document Tree

3.3. PDF Requirements

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

4. Support

4.1. The PLM Portal eAF Guidance materials

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

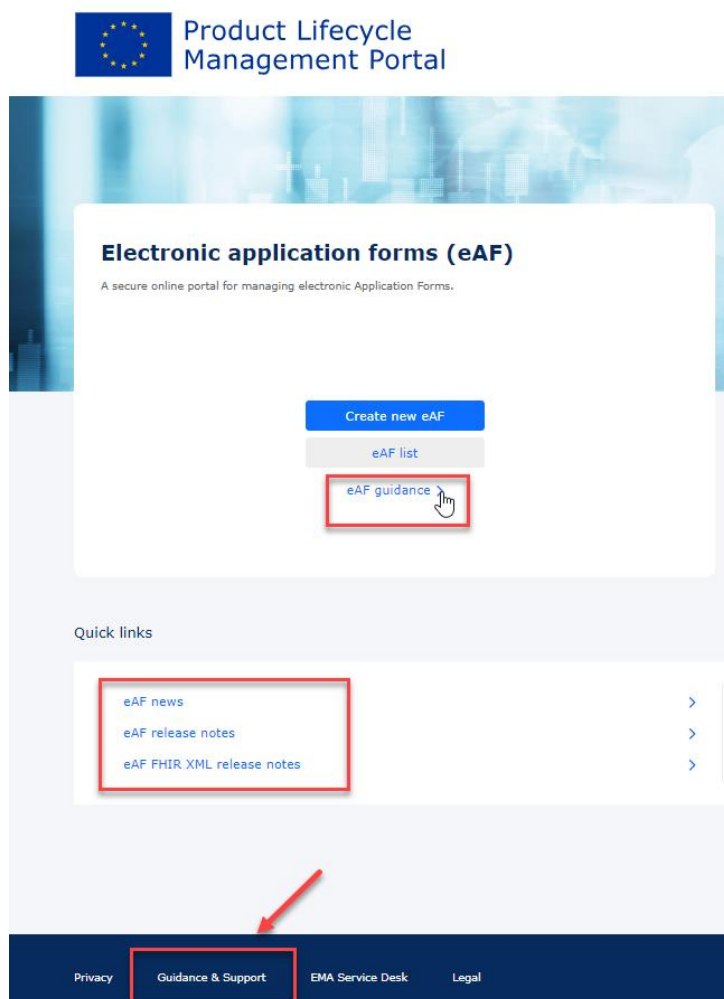


Figure 152 - eAF PLM Portal

4.2. The PLM Forum

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

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

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

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

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



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

4.3. *The Service Desk*

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

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

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

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

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

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

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

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

 Kristiina Puusaari  

* Subject

* Description

* Problem area

* Urgency

-- None -- 


 Add attachments

Figure 153 - Report an Issue with 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

 Kristiina Puusaari  

* Subject

* Description

* Problem area



 Add attachments

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


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

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

4.4. The PLM Chatbot



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

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

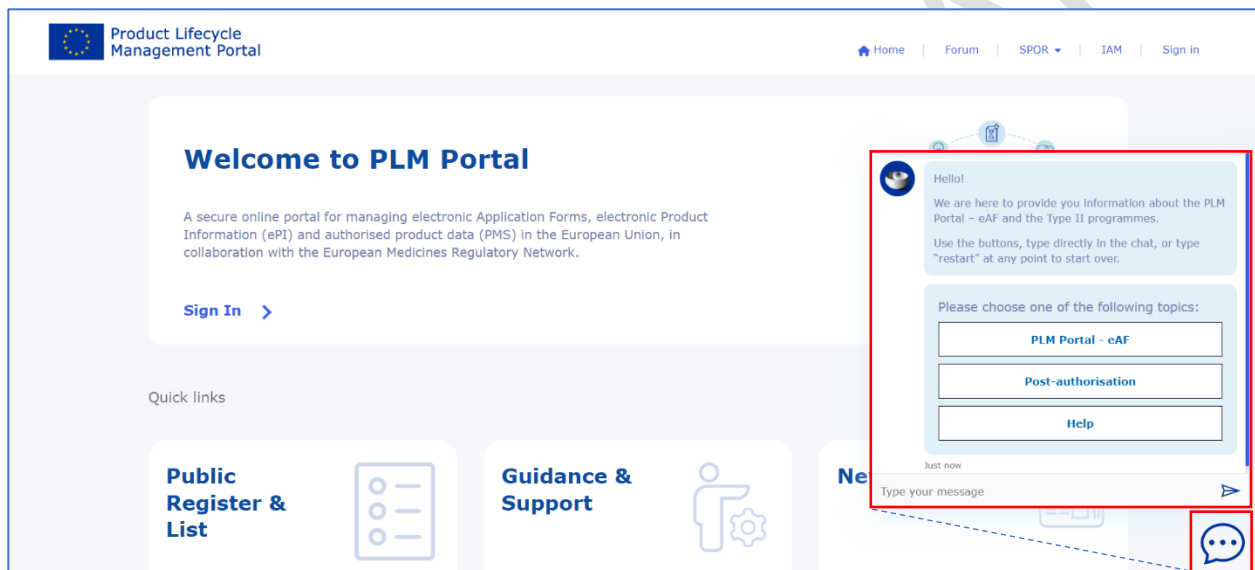


Figure 155 - PLM Chatbot