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Guide to navigation – September 2024 update

Product Lifecycle Management Portal - Human Variations eAF

Version 1.6

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Acronym key and glossary terms

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



1. Purpose and Context

1.1. Purpose of this guide

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

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

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

1.2. *Preliminary requirements*

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

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

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

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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: <u>https://plm-portal.ema.europa.eu/</u>

Product Lifecycle Management Portal		おける			SPOR - IAM Forum Sign in
Electronic application forms (eAF) A secure online portal for managing electronic Application Porma.		Electronic product information (ePI) of on the RVH hord information management, enhancing data accessibility, accuracy, and oblideration across the product lifecycle.		Product Management Ser Product Data Management User Interface (UI), effers se available in the Product Management Services (PHS) da	amless access to product data
eAF guidance >		Published #PIs > ePt guidance >		PHS guidance)	
Quick links					
eAF news eAF release notes eAF FHIR XML release notes	>	eFI news eFI release notes	>	PMS news PMS release notes	>
Privacy Guidance & Support EMA Service Desk Legal					HMA.

2.1.2. How to create a new electronic Application Form

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

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.

Product Lifecycle Management Portal	Spor - IAM Forum Signin
To sign in, you need an active EMA user account with the necessary user access roles. You can create a new user account, apply for user access roles, react your password, or recover your username using the EMA Account Hanagement Partal. To access additional guidance, click on the following link: Guidance & Support - PLH (europa.eu)	Sign in with an EMA Account



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

Electronic application forms + Electronic product in Electronic application forms
New Application Form
Electronic product information (ePI) ePI on the PLM Portal streamlines product information management, enhancing data accessibility, accuracy, and collaboration across the product lifecycle.

Figure 2. New Application Form

3. Click on Create new eAF/New Application Form

eAF list

Create n

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:

Create new ePI

ePI list

Published ePIs >
ePI guidance >

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

In the 1. Select Application Details screen:

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



Figure 3. Application Form Type

Home > Application Forms > Draft Application Form	
1 Select Application Details 2 Add Co-Author	
Application Form Type *	Friendly Name *
Variation Form Human	¥
Reference MAH ()*	
	٩
Create & Next Cancel	

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

Figure 4. Application Details

Home > Application Forms >	> Draft Application Form		
1 Select Application Details 2	Add Co-Author		
Application Form Type * Variation Form Human Reference MAH ①*	 م	Friendly Name * SuperPill 50mg Type II change of AS manufacture	5
Create & Next Cancel			

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

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Draft Deactiv	vated Completed All	Colu	ımn visibility 👻 Refresh ;	🖰 Download 🖥			٩	+ Create New Application Fo
Application Form Id	Friendly Name	Application Form Type	↑ _{Reference MAH}	Created By	Created On	Modified By (Last User)	Modified On (Access Date)	Status
VAR/24/799		Variation Form Human	European Medicines Agency	Kristiina Puusaari	07/05/2024 11:50	Kristiina Puusaari	07/05/2024 14:06	Draft
VAR/24/785		Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 07:15	Kristiina Puusaari	07/05/2024 11:49	Edit Application Form Copy Application Form View/Manage Co-authors
VAR/24/786		Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 07:38	Kristiina Puusaari	06/05/2024 15:41	Deactivate Application Form Exports
VAR/24/791		Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 10:57	Kristiina Puusaari	06/05/2024 13:00	Rename Application Form

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

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

Figure 5. Reference MAH

Home > Application Forms	> Draft Application Form					
1 Select Application Details	2 Add Co-Author					
		Sele	ct Reference MAH			×
Application Form Type *					european medicine	es agency
Variation Form Human		Choos	e one record and click Select to continue			
Reference MAH ()*		~	Organisation Name ↑	Full address	Organisation Id	Organisation Location
Reference MAH ()*			European Medicines Agency	P. O. Box 71010 1008 BA A msterdam Netherlands	ORG-100013412	LOC-100020260
			European Medicines Agency	Domenico Scarlattilaan 6 1 083 HS Amsterdam Netherl ands	ORG-100013412	LOC-100020264
Create & Next Cancel						
				L.		
					Select	Cancel Remove value

Click Select to select the correct MAH from the list. 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/perform a search/filtering as many times as needed.





Figure 6. Create & Next Button

plication Form Type *		Friendly Name *	
/ariation Form Human	× Q	WonderPill Type IA parameter change	
ference MAH ①*			
European Medicines Agency	× Q		
Org ID		LOC ID	
ORG-100013412		LOC-100020264	
Address		Customer Account Number	
Domenico Scarlattilaan 6 Amsterdam 1083 HS		1234567890	
Netherlands		Modified On	
		19/01/2024 11:01	
te & Next			
te & Next Application Forms > Draft Application Form A Application Form A Add Co Author			
> Application Forms > Draft Application Form			
Application Forms > Draft Application Form Sct Application Details 2 Add Co-Author			
Application Forms > Draft Application Form 2 Add Co-Author Application Form Type *		Friendly Name *	
Application Forms > Draft Application Form Sct Application Details 2 Add Co-Author		Friendly Name * X Q Wonderpill 50mg Type II	
Application Forms > Draft Application Form 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH ①*			
Application Forms > Draft Application Form Application Details Add Co-Author Application Form Type * Variation Form Human			
Application Forms > Draft Application Form 2 Add Co-Author Application Details 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH ①* European Medicines Agency			
Application Forms > Draft Application Form Application Details 2 Add Co-Author Application Form Type Variation Form Human Reference MAH ①* European Medicines Agency Org ID ORG-100013412		X Q Wonderpill 50mg Type II	
Application Forms > Draft Application Form Application Details 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH ①* European Medicines Agency Org ID ORG-100013412 Address		X Q Wonderpill 50mg Type II X Q LOC ID LOC-100020264	
Application Forms > Draft Application Form Application Details 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH ①* European Medicines Agency Org ID ORG-100013412 Address Domenico Scarlattilaan 6 Amsterdam 1083 HS		X Q Wonderpill 50mg Type II	
Application Forms > Draft Application Form Application Details 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH @* European Medicines Agency Org ID ORG-100013412 Address Domenico Scarlattilaan 6		X Q Wonderpill 50mg Type II X Q LOC ID LOC-100020264 Customer Account Number 1234567890	
Application Forms > Draft Application Form Application Details 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH ①* European Medicines Agency Org ID ORG-100013412 Address Domenico Scarlattilaan 6 Amsterdam 1083 HS		X Q Wonderpill 50mg Type II LOC ID LOC-100020264 Customer Account Number 1234557890 Modified On	
Application Forms > Draft Application Form Application Details 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH ①* European Medicines Agency Org ID ORG-100013412 Address Domenico Scariattiliaan 6 Amsterdam 1083 HS		X Q Wonderpill 50mg Type II X Q LOC ID LOC-100020264 Customer Account Number 1234567890	
Application Forms > Draft Application Form Application Details 2 Add Co-Author Application Form Type * Variation Form Human Reference MAH ①* European Medicines Agency Org ID ORG-100013412 Address Domenico Scarlattilaan 6 Amsterdam 1083 HS		X Q Wonderpill 50mg Type II LOC ID LOC-100020264 Customer Account Number 1234557890 Modified On	

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



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

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

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

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

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

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

Figure 7. Add Co-author

Home > Application Forms > Draft Application Form					
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		۲
Coordinator(s) with implicit access to this applicat	ion				
Full Name	↑ Contact E-Mail	Role		Role Status	
		No data available in table			
				R	



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

Figure 8. My Organisation Affiliate(s)' Tab



From My Organisation Affiliate(s)	From Other Organisation(s) Column visibility v	Search Q
TFull Name	Role	E-Mail
	Applicant Manager	ema.europa.eu
Save Return		

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

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

Please note that in one go you can add:

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

Click on the Save button

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

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

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

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

Figure 9. Add Co-author



Home > Application Forms > Draft Application Form > Add Co-author	
From My Organisation Affiliate(s) From Other Organisation(s)	
Search User by E-Mail	
	>Authors, Export for viewing medicinal product information not contained in the application products of the organisations the users are affiliated to (including commercially confidential information)
Full Name	1 Contact E-Mail
	r.com
Save Cancel	

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

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

Figure 10. View/Manage Co-authors

ft Deactivate	d Completed All	Col	umn visibility 🐱 Refresh 🧯	🤁 Download 🖥			۹	+ Create New Application
Application Form Id	Friendly Name	Application Form Type	↑ _{Reference MAH}	Created By	Created On	Modified By (Last User)	Modified On (Access Date)	Status
VAR/24/799		Variation Form Human	European Medicines Agency	Kristiina Puusaari	07/05/2024 11:50	Kristiina Puusaari	07/05/2024 14:06	Draft
VAR/24/785		Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 07:15	Kristiina Puusaari	07/05/2024 11:49	Edit Application Form Copy Application Form View/Manage Co-authors
VAR/24/786		Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 07:38	Kristiina Puusaari	06/05/2024 15:41	Deactivate Application Form Exports
VAR/24/791		Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 10:57	Kristiina Puusaari	06/05/2024 13:00	Rename Application Form

Figure 11. Add Co-author

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Home > Application Forms > View/Manage Co-Author				
Co-authors added to this application				
	Ç3			() Add Co-author
Full Name	Contact E-Mail	Role ↑	Role Status	
			Affiliated	•
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	
		No data available in table		

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

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

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

NCA users with an active EMA account and with the eAF Competent Authority User role can edit any existing Application Form from their Member State. Please note that this feature is not yet available as only CAP products are available in the system.

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

Figure 12. Application Forms





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

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

Figure 13. List of Application Forms

Pr Ma									
Home > Application R beactivated		Refresh 🦨 Download 🖥					puusaari euro	٩	+ Create New Applicati
plication em Id	↑Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓Modified On (Access Date)	Status	
AR/24/791	product test	Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 12:57	Kristiina Puusaari	15/05/2024 12:39	Draft	[
R/24/799	error in finalisation	Variation Form Human	European Medicines Agency	Kristiina Puusaari	07/05/2024 13:50	Kristiina Puusaari	15/05/2024 12:37	Draft	
R/24/846	testing adding co-authors	Variation Form Human	European Medicines Agency	Kristiina Puusaari	15/05/2024 12:26	Kristiina Puusaari	15/05/2024 12:26	Draft	
R/24/843	test of pending products	Variation Form Human	European Medicines Agency	Kristiina Puusaari	15/05/2024 09:42	Kristiina Puusaari	15/05/2024 09:42	Draft	
R/24/827	Post deployment check 14 May 24	Variation Form Human	European Medicines Agency	Kristiina Puusaari	14/05/2024 09:14	Kristiina Puusaari	15/05/2024 09:01	Draft	
P					e	lectronic application forms +	Electronic product information + Si		
Home > Application	lanagement Portal	 Refresh gr Devrivad B 				lectronic application forms +	Electronic product information + 5/ punsari euro	POR + IAM For Q	
Home > Application	lanagement Portal	 Refresh @ Dourrised B Application Form Type 	Reference HAH	Created By	El Created On	fectronic application forms + Hoddfied By (Last User)			
Home > Application t Deactivated	Ianagement Portal Forms Completed AI Column visibility v	Application	Reference NAM European Medicines Agency	Created By Kristins Poussari		Hodified By	pusseri euro	٩	
Home > Application t Deactivated plication plication kR/24/791	Ianagement Portal Firms Completed AI Column validity of friendly Name	Application Form Type			Created On	Modified By (Last User)	juusaari euro J.Modified On (Access Date)	Q Status	
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The Application Form(s) are distributed into different tabs, mainly reflecting their possible different statuses: Drafted, Deactivated and Completed and a tab for All the Application Forms.

In all four tabs, you may use:

- the Search Q bar to more quickly find the Application Form you may be looking for,
- the Column visibility button, to hide/unhide columns from the list of Application Form(s),
- the Refresh button, to get the latest list of Application Form(s),
- the Download button, to extract in Excel format, the list of Application Form(s) visible on a specific tab, and,
- *the Create New Application Form button to initiate a new Application Form.*

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

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



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

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

User	Industry	user(s)		NCA user(s)
Role name Application Form Status/tab	(UAT) eAF Applicant Contributor	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	(UAT) eAF Competent Authority User
Draft	 Edit Application Form View/Manage Co-authors 	 Edit Applicati Exports Deactivate A Copy Application View/Manage 	pplication Form tion Form*	
Deactivated	 View Application Form View Co-authors 	 View Applica View Co-auth Exports Copy Applica Reopen Applica Delete Applica 	nors Ition Form* ication Form	
Completed	 View Application Form View Co-authors 	 View Applica View Co-auth Exports Reopen Applica Copy Applica Deactivate A 	nors ication Form	
All	Operations depend on the Status Refer to the above operations and		on Form.	
*	Feature not currently working			

Table 1. Application Form operations

Description of the different operations:



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

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

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

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

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



Home > Application Forms ft Deactivated Completed All	Column visibility 🗸 Refresh 🥫 Dow	mload 🗈	Search	Q + Create New Application For
Application Triendly Name	Application Reference MAH Form Type	I Created By Created On	Modified By Undified On (Last User) (Access Date)	Status
VAR/24/802	Variation Form Human	08/05/2024 00:04	10/05/2024 13:41	Completed 💿
/AR/24/775	Variation Form Human	02/05/2024 13:34	08/05/2024 15:15	View Co-authors Copy Application Form Reopen Application Form
AR/24/744	Variation Form Human	29/04/2024 19:57	07/05/2024 16:50	Exports
/AR/23/141	Variation Form Human	31/01/2023 14:55	07/05/2024 14:24	Completed

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

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

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

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

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

ft Deactivated	Completed All	Column visibilit		ad D		puusaari	· · · · · · · · · · · · · · · · · · ·	Q + Create New Application I
Application Form Id	↑ _{Friendly Name}	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓Modified On (Access Date)	Status
/AR/24/585	New CAPS load	Variation Form Human	European Medicines Agency	Kristiina Puusaari	08/04/2024 14:47	Kristiina Puusaari	08/04/2024 15:36	Completed
VAR/24/407	check following prod deployment 05/03	Variation Form Human	European Medicines Agency	Kristiina Puusaari	05/03/2024 08:05	Kristiina Puusaari	05/03/2024 08:20	View Application Form View Co-authors Copy Application Form
/AR/24/360	Implementation date	Variation Form Human	European Medicines Agency	Kristiina Puusaari	26/02/2024 13:51	Kristiina Puusaari	26/02/2024 16:12	Reopen Application Form
VAR/24/271	2nd copy of test clone clone	Variation Form Human	European Medicines Agency	Kristiina Puusaari	13/02/2024 12:56		15/02/2024 14:07	Exports

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

This feature caters to two different scenarios:

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



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

ect Application Details 2 Add Co-Author		
2 Add Condition		
) Info		
Changing the MAH will clone all information in the application without linking the	nedicinal product to the new draft. Contributors to th	e application will need to select a new MAH
Application Form Type *		Friendly Name *
Variation Form Human	×Q	Demo test ND
Reference MAH ①*		
+ Alpha Pharmaceuticals GmbH	× Q	
Org ID		LOC ID
ORG-100008714		LOC-100017452
Address Kohlenhofstrasse 10 Innenstadt		Customer Account Number
Kalserslautern Rhineland-Palatinate 67663		-
Germany		
		Modified On
		21/11/2022 19:11

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.

p-authors added to this application				Add Co-author
Full Name	Contact Email	Role ↑	Role Status	
Noel Diamant	noel.diamant@ages.at	EMA Admin Assistant	Affiliated	0
oordinator(s) with implicit access to thi	is application			
ull Name	↑ Contact E-Mail	Role	Role Status	
indhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated	



- 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 returning 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.

Full Name Contact Email Role ↑ Role Status	ant Angelineting Details 🖌 🔹				
Ful Name Contact Email Role ↑ Role Status Kristlina Puusaari @ema.europa.eu EMA Admin Assistant Affiliated Image: Contact Ful Name Kristlina Puusaari @ema.europa.eu EMA Admin Assistant Affiliated Image: Contact Ful Name Image: Contact Ful Name Role Status Name	ct Application Details 🖌 💈	Add Co-Author			
Ful Name Contact Email Role ↑ Role Status Kristlina Puusaari Kristlina.Puusaari@ema.europa.eu EMA Admin Assistant Affiliated Image: Contact Email Contact					
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Full Name Contact Email Role ↑ Role Status Kristlina Puusaari Kristlina.Puusaari@ema.europa.eu EMA Admin Assistant Affiliated Image: Contact E-Mail Name ↑ Contact E-Mail Pole Contact E-Mail Applicant Coordinator Affiliated	authors added to this applie	cation			
Kristilna Puusaari Kristilna.Puusaari@ema.europa.eu EMA Admin Assistant Affiliated ordinator(s) with implicit access to this application Name					Add Co-auth
erdinator(s) with implicit access to this application	Full Name	Contact Email	Role ↑	Role Status	
I Name Contact E-Mail Role Status Applicant Coordinator Affiliated	Kristiina Puusaari	Kristiina.Puusaari@ema.europa.eu	EMA Admin Assistant	Affiliated	0
I Name Contact E-Mail Role Status Applicant Coordinator Affiliated					
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Applicant Coordinator Affiliated	ordinator(s) with implicit ac	cess to this application			
Applicant Coordinator Affiliated					
			Role	Role Status	
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Applicant Coordinator Affiliated			J.		
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		∱Contact E-Mail	Applicant Coordinator	Affiliated	
		∱Contact E-Mail	Applicant Coordinator	Affiliated	
		∱Contact E-Mail	Applicant Coordinator	Affiliated	
		∱Contact E-Mail	Applicant Coordinator	Affiliated	



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elect Application Details 🖌 2 Add Co-Author				
co-authors added to this application				Add Co-author
Full Name	Contact Email	Role ↑	Role Status	
Noel Diamant	noel.diamant@ages.at	EMA Admin Assistant	Affiliated	0
coordinator(s) with implicit access to this applica	tion			
Full Name	↑ Contact E-Mail	Role	Role Status	
Sindhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated	
Previous Next Close				
~				

The selected scope is cloned ſ

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	Produ Mana	uct Lifecycle agement Portal		A Home Products Management	nt Service - ePI - Applicatio	n Forms = Forum SPOR =	LAM Noel Dia	mant +
⊃¢	Pending 📓 Type(s) of Chan	gc(s)			Variation	Form Human / Version: 1.110 / Applica		
8	Product Selection	Variations included for this application \oplus Refresh $\ {\cal B}$				Search		Add Scope
X	Type(s) of Change(s)	Scope A.S.b The activities for which the release	e manufacturer/importer is responsible do	Selected on tinclude batch	r/importer of the finishes	CHANGES - Change in the name and/o i product (including batch release or qua ne manufacturer/importer is responsible	lity control testing sites) -	
G	Procedural Information	~	1 Identifier A.5.b - Variation Type IB - 1	Procedure Type X Variation Type 18	Implementation Date	Implementation Date Note	Article 5	•
Ċ	Proposed Changes Pending	1 entries Showing 1 to 1 of 1 entries Save Validate Cencel Excort						
\otimes	Finalisation							



Procedural information will also all be cloned

	Produc Manag	ct Lifecycle gement Portal	A Home	Products Management Service	a∗ ∣ ePI∗ ∣	Application Forms +	Forum	SPOR + LAM	Noel Diamant +	
	Pending 🕱 Procedural Inform	nation				Variation Form Human			ation to a marketing au Last Saved : 06/11/2	
Ô	Product Selection	Please add at least one Contact Person.								
73	Type(s) of Change(s) Pending	Procedural Information							>	
	Procedural Information	Name and Address of MA Holder (Applicant) $\mathbb{O}_{\mathbb{C}}$							>	
ø	Proposed Changes	Contact Person ①							>	
0	Finalisation Pendlog	Save Validats Cancel Export								

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

Pending X Pending X Procedural Info	uct Lifecycle agement Portal		n Home Products Management Service - ePI +	Application Forms - Forum SPOR - 1 Variation Form Human / Vention: 1.110 / Application for Demo test ND / VAR/22/972	
Product Selection Pending	Please add at least one Cont	tact Person.			
Type(s) of Change(s) Pending	Procedural Inform	nation			^
Procedural Information	Domain *	Human ute	Type of Authorisation	Variation Procedure filmber *	
Pending 🛛	Type of Application	Single Regulatory Activity	Name †	Procedure Number †	
	Including a line	0	Decentralised Procedure	P1/N/1234/123	0
Proposed Changes	extension		National Procedure		
● Changes Peoding 又	Worksharing ①				
Finalisation	16 / Supergrouping				
🕑 Pending 🛛 😨	Procedure Type ①		$\label{eq:change} Change(s) \ concern(s) \ (for Type II and Type II \ variations only, tick all changes applicable)$	Reference Member Portugal	~
	Name †				
	Variation Type IB		□ Name		
	2				



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

Product Manager	Lifecycle Application Forme - Forum SPOR - LAM Noal Di ment Portal	amant -
Pending X Proposed Changes	Variation Firm Human / Vention: 1.110 / Application for variation to a ma Domo test ND. / VAR/23/9/22 🕹 Last Saved :	
Product Selection Pending	Precise Scope and Background for Change \odot	>
Type(s) of Change(s) Pendleg Z	Predice Scope for Change * Predice Scope for Change	
Procedural Information Pending		
Proposed Changes Pending	ダ Font ・ B2w ・ B / U ピ・ Δ・ 三 三 ペ キ 三 三 ゆ ペ X, メ キ 副 河 34 2 0 6, E・ Ω	
Finalisation Pending	Background for change and justification for grouping, worksharing and dassification * Background for change and justification for grouping, worksharing and dassification	
	ダ Segment - 9 - 8 / U Z ≧ ≧ = = - + + 用 Ξ = = Φ ≤ X, X - = E 図 14 2 ℃ & =-Ω	
	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 cats needs to be updated. Proposed Change V Search Q Add Present/Pro	posed
	Product HA Number(s) + Scope(s) Recommended Change(s) Proposed Change(s)	
	There are no records to display.	
	Other Applications®	>
	Save Validatà Cancel Deport	

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

2.1.5. Delete form function

The delete form function is not yet available. It is anticipated that this feature will be available before end of Q3 2024.



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

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

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

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

2.2. Product Selection – Updated in September 2024

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

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

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

NCA users with an active EMA account and with the eAF Competent Authority User role can edit any existing Application Form from their Member State. Please note that this feature is not yet available as only CAP products are available in the system.

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

Figure 12. Application Forms





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

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

Figure 13. List of Application Forms

Ma	anagement Portal								
Home > Application R t Deactivated		Refresh 🦪 Download 🖥					puusaari euro	۹	+ Create New Applicati
plication rm Id	Triendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓Modified On (Access Date)	Status	
NR/24/791	product test	Variation Form Human	European Medicines Agency	Kristiina Puusaari	06/05/2024 12:57	Kristiina Puusaari	15/05/2024 12:39	Draft	[
R/24/799	error in finalisation	Variation Form Human	European Medicines Agency	Kristiina Puusaari	07/05/2024 13:50	Kristiina Puusaari	15/05/2024 12:37	Draft	
R/24/846	testing adding co-authors	Variation Form Human	European Medicines Agency	Kristiina Puusaari	15/05/2024 12:26	Kristiina Puusaari	15/05/2024 12:26	Draft	
R/24/843	test of pending products	Variation Form Human	European Medicines Agency	Kristiina Puusaari	15/05/2024 09:42	Kristiina Puusaari	15/05/2024 09:42	Draft	
R/24/827	Post deployment check 14 May 24	Variation Form Human	European Medicines Agency	Kristiina Puusaari	14/05/2024 09:14	Kristiina Puusaari	15/05/2024 09:01	Draft	
Home > Application						ectronic application forms +	Electronic product information + Si		
Home > Application	anagement Portal	 Refresh gr Download B 				ectronic application forms +	Electronic product information + SI	POR + IAM Foru Q	
Home > Application	anagement Portal	 Refresh (2) Downlast (2) Application Jamm Type 	Reference HMI	Created By	E Created On	ectronic application forms - readflied by (Last User)			
Home > Application t Deactivated plication rm Id	Anagement Portal Forms Completed All Column visibility	Application	Reference HAH Europeen Hedicines Agency	Created By Kristina Pausaeri		Modified By	puusaari euro	٩	
Home > Application t Deactivated plication plication plication plication	Ianagement' Portal Firms Complete Al Column vability v Trriently Name	Application Form Type			Created On	Hodified By (Last User)	juusaari euro J.Modified On (Access Date)	Q	
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PM Home > Application t Deactivated plication kR/24/791 kR/24/799 kR/24/B46	Innagement Portal Trrms Complete All Column variability of Promotily Name product text error in finalization	Application Form Type Variation Form Human Variation Form Human	European Medicines Agency European Medicines Agency	Kristiina Puusaari Kristiina Puusaari	Created On 06/05/2024 12:57 07/05/2024 13:50	Modified By (Last User) Kristiina Puusaari Kristiina Puusaari	росами ент 	Q Status Draft Draft Draft Draft	Onade New Appp Onade
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know > Appleader know	Anagement Portal True True True	Application Form Type Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human	European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency	Khatina Puusaari Khatina Puusaari Khatina Puusaari Khatina Puusaari Khatina Puusaari Khatina Puusaari Khatina Puusaari	Created On 06/05/2024 12:57 07/05/2024 13:50 15/05/2024 12:26 15/05/2024 09:42 14/05/2024 09:14 06/05/2024 09:15	Radified by (Sant Uney) Kratine Pussari Kratine Pussari Kratine Pussari Kratine Pussari Kratine Pussari	Jostani eve J. Pledind On (Access bala) 15/05/2024 12:39 15/05/2024 12:37 15/05/2024 12:26 15/05/2024 22:26 15/05/2024 22:26 15/05/2024 22:26 15/05/2024 22:26 15/05/2024 22:26 15/05/2024 22:26	Status Draft Draft Draft Draft Draft Craft	Contro New Appl Contro New Appl Set Application Form New Manage Co-acthor New Manage Co-acthor
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NUME > Application NUME > Application NUME > Description NUM > Application	Anagement Portal Free Complete AI product test product test ferein infinitiation festing adding co-subtras festing adding ad	Application Ferm Type Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human	European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency	Kristine Puusaari Kristine Puusaari Kristine Puusaari Kristine Puusaari Kristine Puusaari Kristine Puusaari Kristine Puusaari Kristine Puusaari	Created On 06/05/2024 12:87 07/05/2024 13:80 15/05/2024 09:42 14/05/2024 09:42 14/05/2024 09:14 06/05/2024 09:15 06/05/2024 09:15	Rodified by (Seat User) Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri	Jucesteir euro J. Pladitioi On (Accesse Data) 15/05/2024 12:39 15/05/2024 12:37 15/05/2024 12:37 15/05/2024 12:36 15/05/2024 12:26 15/05/2024 12:26 15/05/2024 12:37 15/05/2024 12:37 15/05/2024 12:37 15/05/2024 12:36 15/05/2024 12:36 07/05/2024 12:41 06/05/2024 17:41 26/04/2024 02:21	Craft	Consta New Appl Consta New Appl Set Application Form Mau/Manage Co-author ApplAnage Co-author ApplAna
Home > Application	Anagement Portal Free Complete AI product test product test free free free free free free free fr	Application Ferm Type Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human	European Hedicines Agency European Medicines Agency	Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri Kristine Pussaeri	Created On 64/05/2024 12:57 67/05/2024 12:57 15/05/2024 12:26 15/05/2024 12:26 14/05/2024 09:15 66/05/2024 09:15 25/04/2024 09:15 19/04/2024 16:16	Rodina ty Clast twey Kratine Pussari Kratine Pussari Kratine Pussari Kratine Pussari Kratine Pussari Kratine Pussari Kratine Pussari	Putterer Rure Creater Data) 15/05/2024 12:39 15/05/2024 12:39 15/05/2024 12:49 15/05/2024 12:49 15/05/2024 13:49 06/05/2024 13:49 06/05/2024 13:49 26/04/2024 13:49	Q Status Draft Draft Draft Draft Draft Draft Draft Draft Draft	Consta New Appl Consta New Appl Set Application Form Mau/Manage Co-author ApplAnage Co-author ApplAna

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 Q bar to more quickly find the Application Form you may be looking for,
- the Column visibility button, to hide/unhide columns from the list of Application Form(s),
- the Refresh button, to get the latest list of Application Form(s),
- the Download button, to extract in Excel format, the list of Application Form(s) visible on a specific tab, and,
- *the Create New Application Form button to initiate a new Application Form.*

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

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



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

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

Table 1. Applicat	ion Form operations						
User	Industry	user(s)		NCA user(s)			
Role name	(UAT) eAF Applicant	(UAT) eAF	(UAT) eAF	(UAT) eAF			
Application Form Status/tab	Contributor	Applicant Manager	Applicant Coordinator	Competent Authority User			
Draft	- Edit Application Form	- Edit Application Form					
	- View/Manage Co-authors	- Exports					
		- Deactivate Application Form					
		- Copy Application Form*					
		- View/Manage Co-authors					
Deactivated	- View Application Form	- View Application Form					
	- View Co-authors	- View Co-authors					
		- Exports					
		- Copy Application Form*					
		- Reopen Application Form					
		- Delete Application Form*					
Completed	- View Application Form	- View Applica	tion Form				
	- View Co-authors	- View Co-authors					
		- Exports					
		- Reopen Appl	ication Form				
		- Copy Applica	ition Form*				
		- Deactivate Application Form					
All	Operations depend on the Status of the Application Form.						
	Refer to the above operations an	d statuses					
*	Feature not currently working						

Table 1. Application Form operations

Description of the different operations:



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

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

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

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

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



Home > Application Forms					Search		
raft Deactivated Completed All	Column visibility 🐱	Refresh 🧷 Download	3		Search		Q + Create New Application Form
Application Form Id	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓Modified On (Access Date)	Status
VAR/24/802	Variation Form Human			08/05/2024 00:04		10/05/2024 13:41	Completed 💿 View Application Form
VAR/24/775	Variation Form Human			02/05/2024 13:34		08/05/2024 15:15	View Co-authors Copy Application Form Reopen Application Form
VAR/24/744	Variation Form Human			29/04/2024 19:57		07/05/2024 16:50	Exports
VAR/23/141	Variation Form Human			31/01/2023 14:55		07/05/2024 14:24	Completed 💿

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

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

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

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

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

t Deactivated	Completed All	Column visibilit	y 🗸 Refresh 💋 Downlo	ad 🖪		puusaari	(Q + Create New Application
application form Id	↑ _{Friendly Name}	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓Modified On (Access Date)	Status
AR/24/585	New CAPS load	Variation Form Human	European Medicines Agency	Kristiina Puusaari	08/04/2024 14:47	Kristiina Puusaari	08/04/2024 15:36	Completed
AR/24/407	check following prod deployment 05/03	Variation Form Human	European Medicines Agency	Kristiina Puusaari	05/03/2024 08:05	Kristiina Puusaari	05/03/2024 08:20	View Application Form View Co-authors Copy Application Form
AR/24/360	Implementation date	Variation Form Human	European Medicines Agency	Kristiina Puusaari	26/02/2024 13:51	Kristiina Puusaari	26/02/2024 16:12	Reopen Application Form
AR/24/271	2nd copy of test clone clone	Variation Form Human	European Medicines Agency	Kristiina Puusaari	13/02/2024 12:56		15/02/2024 14:07	Exports

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

This feature caters to two different scenarios:

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



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

ect Application Details 2 Add Co-Author		
i) Info		
Changing the MAH will clone all information in the application without linking the n	nedicinal product to the new draft. Contributors to t	he application will need to select a new MAH
Application Form Type *		Friendly Name *
Variation Form Human	×Q	Demo test ND
Reference MAH ①*		
+ Alpha Pharmaceuticals GmbH	×Q	
Org ID		LOC ID
ORG-100008714		LOC-100017452
Address		Customer Account Number
Kohlenhofstrasse 10 Innenstadt Kalserslautern Rhineland-Palatinate 67663		-
Germany		
		Modified On
		21/11/2022 19:11

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.

o-authors added to this application				
-authors added to this application				Add Co-author
Full Name	Contact Email	Role ↑	Role Status	
Noel Diamant	noel.diamant@ages.at	EMA Admin Assistant	Affiliated	O
oordinator(s) with implicit access to thi	is application			
ull Name	† Contact E-Mail	Role	Role Status	
indhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated	



- 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 returning 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.

ect Application Details 🖌 🔰 2	Add Co-Author			
authors added to this applic	ation			
				Add Co-auth
Full Name	Contact Email	Role ↑	Role Status	
Kristiina Puusaari	Kristiina.Puusaari@ema.europa.eu	EMA Admin Assistant	Affiliated	•
rdinator(s) with implicit ac	cess to this application			
l Name	↑Contact E-Mail	Role	Role Status	
		Applicant Coordinator	Affiliated	



(•



elect Application Details 🖌 2 Add Co-Author				
co-authors added to this application				Add Co-author
Full Name	Contact Email	Role ↑	Role Status	
Noel Diamant	ncel.diamant@ages.at	EMA Admin Assistant	Affiliated	0
coordinator(s) with implicit access to this applica	tion			
Full Name	↑ Contact E-Mail	Role	Role Status	
Sindhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated	
Previous Next Close ව				

The selected scope is cloned ſ

.

	Produ Mana	uct Lifecycle agement Portal		A Home Products Management	nt Service - ePI - Applicatio	n Forms = Forum SPOR =	LAM Noel Dia	mant +
⊃¢	Pending 📓 Type(s) of Chan	gc(s)			Variation	Form Human / Version: 1.110 / Applica		
8	Product Selection	Variations included for this application \oplus Refresh $\ {\cal B}$				Search		Add Scope
X	Type(s) of Change(s)	Scope A.S.b The activities for which the release	e manufacturer/importer is responsible do	Selected on tinclude batch	r/importer of the finishes	CHANGES - Change in the name and/o i product (including batch release or qua ne manufacturer/importer is responsible	lity control testing sites) -	
G	Procedural Information	~	1 Identifier A.5.b - Variation Type IB - 1	Procedure Type X Variation Type 18	Implementation Date	Implementation Date Note	Article 5	•
Ċ	Proposed Changes Pending	1 entries Showing 1 to 1 of 1 entries Save Validate Cencel Excort						
\otimes	Finalisation							


Procedural information will also all be cloned

	Produc Manag	ct Lifecycle Jement Portal	A Home	Products Management Service -	ePI =	Application Forms +	Forum SPOR	• LAM N	loel Diamant +	
E	Pending 📓 Procedural Inform	nation					n / Version: 1.110 / Appli Demo test ND / VA			
Ô	Product Selection	Please add at least one Contact Person.								
⊃¢	Type(s) of Change(s) Pending	Procedural Information							>	
	Procedural Information	Name and Address of MA Holder (Applicant) $\ensuremath{\mathbb{O}}$							>	
õ	Proposed Changes	Contact Person ©							>	
ø	Finalisation Pending	Save Validate Cancel Export								

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

	Product Manage	Lifecycle ment Portal		A Home Products Management Service + ePI +	Application Forms - Forum SPOR +	IAM Noel Diamont +
e	Pending 🛣 Procedural Informat	ion			Variation Form Human / Vension: 1.110 / Application fi Demo test ND / VAR/23/97	or variation to a marketing authorisation 72 🛓 Last Saved : 06/11/2023 14:22
8	Product Selection	Please add at least one Con	tact Person.			
ぷ	Type(s) of Change(s) Pending	Procedural Infor	mation			^
G	Procedural Information	Domain *	Human ute	Type of Authorisation	Variation Procedure Number *	
	Pending	Type of Application	Single Regulatory Activity	Name †	Procedure Number †	
Ì	Proposed Changes	Including a line extension	0	Decentralised Procedure National Procedure	PT/NV1234/123	0
	Pending	Worksharing ①				
CI.	Finalisation	16 / Supergrouping				
\odot	Pending 🔀	Procedure Type ①		Change(s) concern(s) (for Type II) and Type II variations only, tick all changes applicable)	Reference Member Portugal State	*
		Name †				
		Variation Type IB		□ Name		



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

Product Manage	Lifecycle roducts Management Service - eFL - Application Forms - Forum SPOR - JAM Noel ment Portal	Diamant -
Pending X Proposed Changes	Variablen Form Human / Version: 1.110 / Application for variablen to a n Domo test ND / VAV/23/972 🛃 Last Saved	
Product Selection Pending	Precise Scope and Background for Change ⊙	>
Type(s) of Change(s) Pending	Precise: Scope for Change * Precise: Scope for Change #	
Procedural Information Peoding		
Proposed Changes Pending		
Finalisation Pending	Background for change and justification for grouping, worksharing and classification * Itackground for change and justification for grouping, worksharing and classification	
	d' Segenti • 8 / U ⊉• <u>[a</u> * = = = = * * ∰ ≡ ≡ ⊕ ⊕ ×, × = ₩ [2] % 2 ⊂ 5 ≡• Ω	
	Present and Proposed Changes	^
	Rease add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based on your acceps selection. In addition to free text / Organisation changes; please theck if structured product data needs to be updated.	roposed
	Product HA Number(s) + Scope(s) Recommended Change(s) Proposed Change(s)	
	There are no records to display.	
	Other Applications [®]	>
	Seve Vulidata Cancel Export	

- 3. 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.
- 4. Please note that any 'Other applications' that have been selected in the original application will also be cloned. If you are changing the product, **please manually delete** the previously selected procedure numbers related to other products. Please note that this is a bug which will be addressed in a future release.

2.2.3. Delete form function

The delete form function is not yet available. It is anticipated that this feature will be available before end of Q3 2024.



2.2.4. How to add a product in an Application Form

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

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.

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.

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

- **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 + Add Product button. Upon clicking this button, an empty search grid will appear.

Please note that the field with the magnifying glass \mathbf{Q} has been renamed to 'filter' to reflect that it is not actually a search field to find products, but to 'filter' a list of displayed products or already selected products (this can be only used when editing a form that already has some products selected). Products cannot be searched/added using this field.

Figure 14. Add Product



Ø	Product Selection Pending		erned by this applica				As	sociate MRP N	r. Sea	rch		Q + Add Produc	ct
以	Type(s) of Change(s) Pending	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	
	Procedural Information Pending	Showing 0 to 0 of	0 entries		N	lo data availabl	le in table	2					

A new search grid has been implemented as a part of the 'performance improvements' in preparation for the inclusion of the non-CAPs into the form.

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

	$\langle \bigcirc \rangle$	Product Life Managemer	ecycle nt Portal			Electronic ap	plication forms - Electron	nic product information +	Products Ma	nagement Ser	rvice + SPOR + IAM	Forum Kristiina Puusaari	-
	nding 🔀 roduct Selecti	ion > View / Select	Product						Variatio			cation for variation to a marketi /24/1156 土 Last Saved : 17	
8	Column visibili	ity 🗸 Refresh 🞜 Shi	ow 10 rows 👻 Clear Filters	View Selected Products						Filter			
>\$	0	↑ ^{Full} Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID		MP ID	RPI	
_	۹	Search Full Name	Search Authorised Dose Form	Search Active substance(s)	Search Authorisation Country	Search MA Holder	Search MA Nr.	Search MRP/CP Nr.	Search PHS 1	D	Search MP ID	Search RPI	
						No data available ir	i table						
\odot	Showing 0 to		s selected									l⊋	
8						~							

In the Select Product subpage, use available fields for triggering the product search to select the applicable product(s). Different columns are available to allow users to select their preferred search criteria from the existing columns. Depending on the number of products available for each user the list may need to be filtered with multiple attributes.

Start the search by typing into the field and click `**enter'** to start the search or click the magnifying glass \mathbf{Q} to the left of the search filters.

Note that the list 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.



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🗁 de

	∱Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
٩	Search Full Name	tablet	Search Active substanc	european union	Search MA Holder	Search MA Nr.	Search MRP/CP Nr.	Search PMS ID	Search MP	Search RPI
0	ABILIFY 10 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60000000449		PRD/00000743
	ABILIFY 10 mg tablets	Tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60000002516		PRD/00000736
	ABILIFY 15 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60000000450		PRD/00000734
	ABILIFY 15 mg tablets	Tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60000001694		PRD/00000725
0	ABILIFY 30 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60000004293		PRD/00000743

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.

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 new maintenance pop up window. Please note that the duration that further actions on the form are blocked by the pop up depends on the number of selected medicinal products and the number of available packages for those medicinal products. We are currently looking at ways to reduce the timing that it takes to perform these background activities:

Just a moment		
Please wait while the selected products are added in your application.		
	Return Ref	fresh

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.

9	
EUROPEAN MEDICINES	

	↑ ^{Full} Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	РМ
٩	Search Full Name	tablet	Search Active substance	european union	Search MA Holder	Search MA Nr.	Search MRP/CP Nr.	Searc
	ABILIFY 10 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60
	ABILIFY 10 mg tablets	Tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60
	ABILIFY 15 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60
	ABILIFY 15 mg tablets	Tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60
	ABILIFY 30 mg orodispersible tablets	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471	60

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

Figure 15. List of Products

↑Full Name Authorised Dose Form Active substance(s) Authorisation Country MA Holder MA Nr. ↑MRP/CP Nr. PMS ID MP ID RPI ABASAGLAR 100 untr/mL ref.filed pen Solution for injection in a pref.filed pen Solution for injection for injection in a pref.filed pen Solution for injection for injection in a pref.filed pen Insulin glargine European Union Eli Lilly Nederland B.V. EU/1/14/944 EMEA/H/C/002835 Image: Country in the pen pen/filed pen Image: Country in the pen pen filed pen Image: Country in the pen pen Im	Colur	nn visibility 🗸 🤉 Refre	sh 🧷 Show 10 ro	ws 👻 View Selec	ted Products				EMEA/H	1/C/002	
Image: Notice of the solution for solution for injection in a pre-filled pen solution for injection in a pre-filled pen solution for injection in a pre-filled pen solution for injection in a solution for		∱Full Name				MA Holder	MA Nr.	↑MRP/CP Nr.	PMS ID	MP ID	RPI
100 units/mL Tempo Pen Solution for Insulin European Eli Lilly Solution for injection glargine Union Nederland B.V. injection in a		100 units/mL KwikPen solution for injection in a					EU/1/14/944	EMEA/H/C/002835			
		100 units/mL Tempo Pen solution for injection in a					EU/1/14/944	EMEA/H/C/002835			

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

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 16. View Available Products

Colu	umn visibility 👻 🛛 Re	efresh 🖉 Show 10	0 rows 👻 Clear F	ilters View	Available Produ	icts			Filter		
							ß				
	Full Name	Authorised Dose Form	↓Active substance(s)	Author s) Countr		IA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
٩	Search Full Name	Search Authorised	Search Active s	ubsti Search	Authorisatis	Search MA Holder	Search MA Nr.	Search MRP/CP Nr.	Search PMS ID	Search MP ID	Search RPI
	Aderolio 0,2! tabl										10
	Ade 0,5 tabl										49
	Ade 0,7! tabl										89
	Ade 1,0 tabl										87
	Afin mg tablets			Union	Limited						. 36
	Afinitor 2.5	Tablat	Cusarianus	European	Novartis			EMEA/UL/CIOO1000	600000000000		000/0000202255

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 <u>Medicinal Products</u> option (you will need to be signed in to see the list content). This will open a full list of authorised products.

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





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

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

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

is concerned by this application 🛈 visibility ~ Show 10 rows Refresh 🎜				Associate MRP Nr. S	arch Q + Add I
Full Name		Authorised Active Dose Form Substance	Authorisation MA Country Holder	MA Nr. OMRP / CP	Nr. of PMS 10 Selected
ABILIFY 1 mg/ml oral solution			Union Union Disuka B,V.		Packages 0/3
Selected Packaged Medicinal Product(s)					Search
Full Name	Pack Size	Package Description	MA Number	1 Package ID	Authorisation Status
ABILIFY 1 mg/ml oral solution	1 bottle + 1 cup + 1 calibrated dropper	Packaging: bottle (PET), Package size: 1 bottle + 1 cup + 1 calibrated dropper, Content: 50 ml	EU/1/04/276/033		Valid - Transferred marketing authorisation
ABILIFY 1 mg/ml oral solution	1 bottle + 1 cup + 1 calibrated dropper	Packaging: bottle (PET), Package size: 1 bottle + 1 cup + 1 calibrated dropper, Content: 150 ml	EU/1/04/276/034		Valid - Transferred marketing authorisation

Figure 17. Packaged Medicinal Product(s)

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

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



\mathcal{O}_{\ominus}	Completed Product Selection												tion to a marketing authorisa ved : 09/09/2022 13:12:00
Ø	Product Selection	Products c	concerned by this a	oplication									
	Completed 🥥	Col	lumn visibility 🗸 S	how 10 rows R	tefresh 💋					Associate MRP Nr.	Search	۹	+ Add Product
ぷ	Type(s) of Change(s) Pending		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
	Procedural Information	~	Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG- 200036101) LOC	1- 19575UAT		UAT600010687758	600010687758		0/0
- -	Pending Proposed Changes Pending X		a 1 of 1 entries	Export									

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

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

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

Figure 19. Associate MRP Nr. Button



(∇_{-})	Completed Selection												tion to a marketing autho ved : 09/09/2022 13:12
Ø	Product Selection		concerned by this a olumn visibility v S		tefresh <i>B</i>					Associate MRP Nr.	Search	٩	+ Add Product
ぷ	Type(s) of Change(s) Pending		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
	Procedural Information	Showing 1 to	Advantan 0,1% - Creme o 1 of 1 entries	Cream		Republic of Austria	UAT ORG (ORG- 200036101) LOC	1- 19575UAT		UAT600010687758	600010687758		0/0
\mathbf{O}	Proposed Changes Pending X		Validate Cancel	Export									

2.2.6. How to delete a product from an Application Form

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

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

+ Add Product
Selected Jes

- **3.** Click on <u>View Selected Products</u> to have a glance at the products you have tick marked. You may switch between that view and the <u>View Available Products</u> view to go back to the full list of selectable products.
- **4.** In the Select Product subpage, un-tick the product(s) click the <u>View Selected Products</u> 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, but not the tick box). You may want to use the filters or the filtering field to further define your displayed products list.

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

Figure 21. View Available Products

Figure 20. Add Product



Colu	nn visibility 🐱 Refi	resh 💋 Show 10 row	s 👻 Clear Filters	View Available Pro	oducts			Filter	
					_				
	↑Full Name	Authorised Dose Form	Active substance(s)	Authorisati Country	on MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID RPI
٩	Search Full Name	Search Authorised Do	Search Active sul	Search Authori	sation Search MA Hold	er Search MA Nr.	Search MRP/CP Nr.	Search PMS ID	Search MP II Search RPI
2	Humalog 100 U/ml - Suspension for injection	Suspension for injection	Insulin lispro	European Union	Eli Lilly Nederland B.V.	EU/1/96/007	EMEA/H/C/000088	60000002033	PRD/000007144
2	Humalog 100 U/ml - Suspension for injection	Suspension for injection	Insulin lispro	European Union	Eli Lilly Nederland B.V.	EU/1/96/007	EMEA/H/C/000088	60000001966	PRD/000007202
ø	Humalog 100 units/ml Junior KwikPen solution for injection in a pre-filled pen	Solution for injection	Insulin lispro	European Union	Eli Lilly Nederland B.V.	EU/1/96/007	EMEA/H/C/000088	600000993317	PRD/000169194;
	Humalog 100 units/ml KwikPen solution for	Solution for	Insulin lispro	European Union	Eli Lilly Nederland B.V.	EU/1/96/007	EMEA/H/C/000088	600000993320	PRD/000169102

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

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

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

2.3. Type(s) of change(s)

2.3.1. How to add a variation scope in an Application

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

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

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



- 1. Access an existing or create a new Application Form. See sections **Error! Reference source not found.**, 2.1.2and 2.1.3 for further details
- 2. In the Type(s) of Change(s) page, click on Add Scope

Figure 22. Add Scope

С\$	Pending 🚡 Type(s) of Chang	je(s)			
œ	Product Selection	Variations included for this application ${}^{}$. Refresh ${}^{}$			Sarah kidi Scope
	Type(s) of	↑ Scope	Selected	Description	
	Change(s)			No data available in table	
	y Procedural	Save Validate Cancel Export			

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

Figure 23. Select Scope

以	Perding ∑ Type(s) of Change(s)> Add/Edit Scope	
<i>8</i> 6	Selected Scope	
≫\$		
	Save Cancel	

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

Figure 24. Example of Search using Classification Code



\sim	Selected Scope		
$\neg \rangle$	Select Scope		To search on partial text, use the asterisk (*) wildcard character.
~~			c.i Q
	Choose one record and click S	elect to continue	
	~	Name ↑	
		C.1.1.a The medicinal product is covered by the defined scope of the procedure	
۳		C.I.1.b The medicinal product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submit	tted by the MAH
— I		C.I.I.c The medicinal product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure with new additional data submitted by the MAH	
\rightarrow		C.I.10 Change in the frequency and/or date of submission of periodic safety update reports (PSUR) for human medicinal products	
\bigcirc		C.I.11.a Implementation of wording agreed by the competent authority	
		C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required.	uired*
		C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II	
\bigcirc		C.1.11.2 Other obligations and conditions (e.g. acreed wording + ORD template)	
\odot	< 1 2 3 4	5 >	
<u> </u>			
			Select Cancel Remove value

Figure 25. Example of Search using Wild Card and Text

Select Scope	3	×
		*atc Q
Choose one record and click	Select to continue	L
~	Name 1	
	A.5.a The activities for which the manufacturer/importer is responsible include batch release	
	A.S.a The activities for which the manufacturer/importer is responsible include batch release	
	A.S.b The activities for which the manufacturer/importer is responsible do not include batch release	
	A.6 Change ATC Code / ATC Vet Code	
	A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch rial, reagent or excipient (when mentioned in the dossier)*	ontrol takes place, or supplier of a starting mate
	B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place	
	B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological active substance replacement or addition of a site where batch control/testing including a biological active substance replacement or addition of a site where batch control/testing including a biological active substance.	al / immunological / immunochemical method ta
< 1 2 3 >		
		Select Cancel Remove value

- 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**.
- Click on the Select button. If you wish to cancel and not select any scopes, click on the Cancel button

Upon clicking the <u>Select</u> 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 \mathbf{Q} again to return to the scope selection window.

Figure 26. Cancel and Select Scope

\mathcal{O}_{Θ}	Selected Scope	_	
	C.I.6.a Addition of a new therapeutic indication or modification of an approved one	×	۹
		-	_

7. Click on the magnifying glass \mathbf{Q} to `Select Procedure Type'



Figure 27. Select Procedure Type

Selected Scope				
C.I.6.a Addition of a new	v therapeutic indication or modification of an approved one	×	۹	
Select Procedure Type				
		_	٩	Launch lookup modal
Identifier	Select procedure type from the list			

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

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

Figure 28. Select Procedure Type

Select Procee	Јиге Туре	×
		Search Q
Choose one record and click S	ielect to continue	
~	Name 🕆	
	Variation Type II	
	Variation Type II Art. 29	
	[Select Cancel Remove value

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



Figure 29. Option Selection

Selected Scope *		
B.I.b.2.a Minor changes to an approved test procedure X		
Select Procedure Type *	Implementation Date *	
Variation Type IA X Q	DD/MM/YYYY	
Identifier •		
B.I.b.2.a - Variation Type IA - 1		
Implementation Date Note		
L		
		1.
Select Conditions		
□ Conditions ↑	Note (i)	
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.	6	•
Select Documentations		
□ Cocumentations ↑	Note ①	
Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for vet many products, as appropriate), including a description of the analytical methodology, a summary of validation data, revis d specifications for impurities (if applicable).	G	•
Comparative validation results or if justified comparative analysis results showing that the current test and the propose one are equivalent. This requirement is not applicable in case of an addition of a new test procedure.		•
Save Cancel		

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

Depending on the selected procedure type, related Conditions and Documentations will be listed. Please select as appropriate. Please note that selection of conditions and documentations or adding a note is mandatory. If you do not meet the conditions or cannot provide the documentation, please add a note using the small arrow on the right-hand side. This will launch a free text field for note/justification.

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

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

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



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

Figure 30. Summary of Selection

8	Product Selection	Variations include Refresh	ed for this application()	D						Search	Add Scope
	Turpo(c) of		Scope			Selected		Description			
X,	Type(s) of Change(s)	$\widehat{}$	B.I.b.2.a Minor change	s to an approved test procedure		1		Change in test procee material/reagent/inte	CHANGES - ACTIVE SUBSTANCE - Con Jure for active substance or starting irmediate used in the manufacturing p anges to an approved test procedure		•
	Procedural Information Pending X	~		Identifier B.I.b.2.a - Variation Type IB - 1	Procedure Type Variation Type IB		Implemen	tation Date	Implementation Date Note	Article 5	
$\mathbf{\vec{o}}$	Proposed Changes Pending X	1 entries									
		Save Validate	e Cancel Export								

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

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

Figure 31. Add Scope



Variations inc	uded for this application ${}^{}$					
Refre	sh <i>C</i> r				Search	Add Scope
	[↑] Scope		Selected	Description		
Ì	C.I.6.a Addition of a new therapeutic indication or m	odification of an approved one	2	C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE NARY MEDICINAL PRODUCTS - Change(s) to thera new therapeutic indication or modification of an ap	peutic indication(s) - Addition of	
	[↑] Identifier	Procedure Type	Implementation Da	te Implementation Date Note	Article 5	
\sim	C.I.6.a - Variation Type II - 1	Variation Type II				۲
\sim	C.I.6.a - Variation Type II - 2	Variation Type II				٢
2 entries Showing 1 to 1 Save Vali	of 1 entries date Cancel Export					

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

2.3.2. Clone scope

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

↑ Scope	Selec	ted	Description						
A B.I.b.2.a Minor changes to an approved test procedure	3		B.I.b.2.a - QUALITY CHANGES - ACTIVE SU active substance or starting material/reage ance - Minor changes to an approved test p	nt/intermediate used in the manufacturir					
	1 Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5				
^	B.1.b.2.a - Variation Type IB - 1	Variation Type IB							
↑ Selected	Condition		Note						
a	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.								
5		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).							
8	The text method is not a biological/immunological/immunochemical method, or a method using a biological respect for a biological active substance (does not include standard pharmacopoeial mic robiological methods).								
8	There have been no changes of the total d.	impurity limits; no new unqual	fied impurities are detecte						
4 entries									
↑ Selected	Documentation		Note						
8	Amendment of the relevant section(s) of me 6B format for veterinary products, ar thodology, a summary of validation data	s appropriate), including a descr	iption of the analytical me						
1	Comparative validation results or if justil test and the proposed one are equivalen of a new test procedure.								



fresh Ø				Search		Add Scop
↑ _{Scope}	Selected		Description			
8.1.b.2.a Hinor changes to an approved test procedure	1		B.I.b.2.a - QUALITY CHANGES - ACTIVE SU stance or starting material/reagent/interme to an approved test procedure	IBSTANCE - Control of active substance adiate used in the manufacturing proces	 Change in test procedure s of the active substance - 	for active sub Minor changes
	↑ Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5	
/	B.I.b.2.a - Variation Type IB - 1	Variation Type IB				0
						Edit Scope Clone Scope Ba
ies .						Delete

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

Scope Selected Description B.L.b.Z.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Consultance or Stating material/regulations or	Variations included for this application	D					
Stope Stelected Description B.L.b.2.a Winor changes to an approved test procedure Implementation Date Implementation Date Implementation Date Note Article 5 B.L.b.2.a - Variation Type IB - 2 Variation Type IB - 3 Variation Type IB -	Refresh 💋				Search		Add Scope
B.b.b.2.a Minor changes to an approved test procedure 3 test procedure for active subtance or starting material/reagent/intermediate used in the main ufacturing process of the active subtance - Minor changes to an approved test procedure Implementation Date Implementation Date Note Article 5 B.b.b.2.a - Variation Type IB - 1 Variation Type IB - 2 Variation Type IB - 2 Variation Type IB - 2 B.b.b.2.a - Variation Type IB - 3 Variation Type IB - 3 Variation Type IB - 2 Variation Type IB - 2 Variation Type IB - 2 Intries Use State St	↑ _{Scope}		Selected	Description			
B.I.b.2.a - Variation Type IB - 1 Variation Type IB B.I.b.2.a - Variation Type IB - 2 Variation Type IB B.I.b.2.a - Variation Type IB - 3 Variation Type IB B.I.b.2.a - Variation Type IB - 3 Variation Type IB	A B.I.b.2.a Minor changes to a	an approved test procedure	3	test procedure for active subs	stance or starting material/reagent/into	ermediate used in the	man 🕑
B.I.b.2.a - Variation Type IB - 2 Variation Type IB B.I.b.2.a - Variation Type IB - 3 Variation Type IB		↑ Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5	
B.I.b.2.a - Variation Type IB - 3 Variation Type IB Intries Edit Sco Delete	\sim	B.I.b.2.a - Variation Type IB - 1	Variation Type IB				٢
ntries Edit Sco Delete	\sim	B.I.b.2.a - Variation Type IB - 2	Variation Type IB				•
Clone Sc Delete	\checkmark	B.I.b.2.a - Variation Type IB - 3	Variation Type IB			_	۲
Delete							Clone Scope V
housing 1 to 1 of 1 poten	ntries						
Save Validate Cancel Export	Showing 1 to 1 of 1 entries					_	

• 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.

Refresh					Search	
	↑ Scope	Selec	ted	Description		
^	B.T.b.2.a Minor changes to an approved test procedure	3		B.I.b.2.a - QUALITY CHANGES - ACTIVE SU active substance or starting material/reage ance - Minor changes to an approved test p	BSTANCE - Control of active substance - Change in test proc tt/intermediate used in the manufacturing process of the ac rocedure	edure for ive subst
		1 Identifier	Procedure Type	Implementation Date	Implementation Date Note Article 5	
\sim		B.I.b.2.a - Variation Type IB - 1	Variation Type IB			
\sim		B.I.b.2.a - Variation Type IB - 2	Variation Type IB			
\sim		B.I.b.2.a - Variation Type IB - 3	Variation Type IB			

2.3.3. How to delete a scope in an application

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

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



2. In the Type(s) of Change(s) page, click the small arrow at the end of the scope you wish to delete and select 'Delete'.

Figure 32. Delete Scope

<i>0</i>	Product Selection	Variations included for this application ${}^{}$. Refresh ${}^{}_{\mathcal{S}}$			Search Add Scope
>\$	Type(s) of Change(s) Pending	Scope S.I.b.2.a Minor changes to an approved test procedure	Selected	Description B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control Change in test procedure for active substance or starting material/resemultamentation used in the manufacturing process substance - Minor changes to an approved test procedure	
	Procedural Information Pending X	Save Validate Cancel Export			

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

conditions/documentations where relevant. Please click save to save the selection.

Figure 33. Edit Scope

Refresh 🖉					Search	Add Scop	
î s	Бсоре		Selected	Description			
^ 0	C.I.6.a Addition of a new therapeutic indication or mo	odification of an approved one		NARY MEDICINAL PRODUCTS - Change(s) to there	- SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERI EDICINAL PRODUCTS - Change(s) to therapeutic indication(s) - Addition of a rapeutic indication or modification of an approved one		
	1 Identifier	Procedure Type	Implementation Dat	te Implementation Date Note	Article 5		
\sim	C.I.6.a - Variation Type II - 1	Variation Type II				٢	
\sim	C.I.6.a - Variation Type II - 2	Variation Type II			•	Edit Scopen	

2.3.4. How to delete a scope in an application

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

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

Figure 34. Delete Scope

<i>0</i>	Product Selection	Variations included for this application $^{\textcircled{O}}$. Refresh $\mathcal B$		Search	Add Scope
3	Type(s) of Change(s) Pending	 Scope B.I.b.2.a Minor changes to an approved test procedure 	Selected	Description B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure	- Delete
	Procedural Information	Save Validate Cancel Export			

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



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

Figure 35. Edit Scope

ariations includ	led for this application (\hat{i})						
Refresh	Ø					Search	Add Scope
	Scope		Selected	Description	1		
^	C.I.6.a Addition of a new therapeutic indication	 C.I.6.a - SAFETY, EFFICACY, PHARMACOVIG NARY MEDICINAL PRODUCTS - Change(s) to new therapeutic indication or modification or 		CINAL PRODUCTS - Change(s) to therap	therapeutic indication(s) - Addition of a		
	[↑] Identifier	Procedure Type	Implementation	Date	Implementation Date Note	Article 5	
\sim	C.I.6.a - Variation Type II - :	Variation Type II					٢
\sim	C.I.6.a - Variation Type II - 2	2 Variation Type II					Edit Scope

2.4. Procedural Information

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

Figure 36. Procedural Information Section Overview

	Product Selection	Procedural Information	>
<i>ж</i>	Type(s) of Change(s)	Name and Address of MA Holder (Applicant)	>
ē	Pending X	Contact Person	>
l≡	Information Pending	Save Volidate Cancel Export	

2.4.1.Procedural Information

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

It is not possible to manually edit these selections.

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



Figure 37. Sub-section: Procedural Information

Procedural Information		^
Domain Human use	Type of Authorisation	Variation Procedure Number
Type of Application Single Regulatory Activity Worksharing ①	Name ↑ Centralised Procedure	Procedure Number ↑
IG / Supergrouping ()		There are no records to display.
Procedure Type ① Name ↑	Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)	
Variation Type II	Name indication Paediatric requirements Quality Annual variation for human influenza Variation to changes related to the active subtance of a human coronavirus vaccine Medical devices Other	

- Domain: This is always 'Human Use' as the variation form only contains human medicinal products.
- Worksharing; this field is auto calculated and is ticked by the system when more than one 'Centrally Authorised Products' (CAPs) i.e. products with different EMEA/H/ number have been selected. Please note that the product selection is on 'Medicinal Product' level i.e. if the product selected has for example more than 1 pharmaceutical forms, and your change impacts all 'medicinal products' you should select them all, but this does not mean that the work-sharing tick box will be ticked.
- *IG/Super grouping; If more than one CAP has been selected and in addition to one or more Type IA and/or Type IA_{IN} scopes have been selected.*
- Procedure Type; this field will display the name(s) procedure type(s) selected in the Type(s) of Change(s) section (For example Variation Type II).
- Type of Authorisation; This field is auto filled based on the type of authorisation procedure of the selected product(s). For now, this is always Centralised Procedure as non-CAPs are not yet available in the system. If you need to submit a work-sharing application containing both CAPs and NAPs (MRP/DCP/NP), please use the pdf format eAF only.

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

- Medical Device; this tick box is available for all procedure types and should be selected if the section 4d of the pdf needs to be filled i.e. for classifications (scopes) related to Medical Devices e.g. B.IV.1.a.1.
- Change(s) concern(s); this sub selection is only visible if Type IB or Type II has been selected in Type(s) of Change(s) section. 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.

	Type of Authorisation	Variation Procedure Number	+ Add
ity	Name 1	Procedure Number ↑	
Variation P	rocedure Number	There are no records to display. Variation Procedure Numbers 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 'Bet Practice Guides for the submission and processing of variations in the Mutual Recognition Procedure' (http://www.ma.eu). Veterinary Medicinal Products: Variation number to be issued by the Reference Member State before submission of the application according to the corresponding VMRFG Best Practice Guide (http://www.hma.eu). Centralised Procedure: The sequential EMA procedure number (not the MAH's internal number) should be provided here, when Known to the Marketing Authorisation Holder. For Worksharing procedures with EMA as reference authority, the 'high-level' EMA worksharing procedure number needs to be provided.	
icant)		Purely nationally authorised products: Number to be completed according to requirements of the relevant National Competent Authority	>

Figure 38. Variation Procedure Number

2.4.2.Name and Address of MA Holder (Applicant)

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

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



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

Name and Address of MA Holder (Applicant)		^
Reference MAH ① European Medicines Agency		
Org ID	LOCID	
ORG-100013412	LOC-100020264	
Address Domenico Scarlattilaan 6 Amsterdam 1083 HS Netherlands	Customer Account Number — Modified On 12/09/2022 19:09	
Phone Number	Email	_
Provide a telephone number		
		_

2.4.3. Contact Person

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

1. Click the + Add button

Contact Person							^
Selected Contacts							+ Add
Member State	Title	First name	Surname	Telephone	E-Mail	Company 🛧	Add
There are no records t	to display.						

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

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



Figure 41. Create Application Contact

Create Application Contact	×
First name	Surname
Email	Phone
	Provide a telephone number
Title	Member State
	×
Company	
٩	
Save	

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

Figure 42. Lookup Records

Looku	up records	 i enorme a selectrone no 		×
				*iaitos Q
Choose (one record and click Select to continue			
~	Organisation Name 🕇	Full address	Organisation Id	Organisation Location
	Terveyden Ja Hyvinvoinnin Laitos	Mannerheimintie 166 00300 Helsinki Helsinki-Uusimaa Finland	ORG-100019555	LOC-100039037
	Terveyden Ja Hyvinvoinnin Laitos	PI 30 00271 Helsinki Finland	ORG-100019555	LOC-100039039
				Select Cancel Remove value

- 4. Click on the Select button and you will be taken back to the Create Application Contact page
- 5. Click on the Save button and you will be taken back to the Procedural Information main page
- **6.** Click on the <u>Save</u> button to save your changes. You may want to click on the <u>Validate</u> button to change the status of this section to <u>Completed</u>

2.5. Proposed Changes

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

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



Figure 43. Proposed Changes

\odot	Pending 🚡 Proposed Changes		
0	Product Selection	Precise Scope and Background for Change	>
ズ	Type(s) of Change(s)	Present and Proposed Changes	>
	Procedural	Other Applications	>
<u>l</u> ≡	Pending	Save Validate Cancel Export	
C	Proposed Changes Pending		

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 **Error! Reference source not found.**, 2.1.2and 2.1.3 for further details
- 2. Enter the Precise Scope for Change and Background for change in the corresponding free text fields. You can paste text into this field from another document (plain text only will be copied, you will need to manually edit the text if you wish to add for example <u>underlined</u> or **bold** text. You can also add images and tables.

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

Precise Scope and Background for Change	Precise Scope and Background for Change		
Precise scope for change	Specify the precise present and proposed working or specification, Hockding double level, excision numbers), if the lowest possible level, Chick here to read the guidance. Guidance for applicants for the segmentation of the precise scope section of the variation application form		
Size • B / U	<u>ℓ• ∆•</u> ≡ ≔ •= •= •	医苦菌 やう ちざゃ 眉子 作う くる 言・ Ω	
State forct.	£• ∆• ⊞ ≔ •= =	副 圏 泡 ペ ス オ ベ 副 托 乳 ラ ぐ る ■・Ω	
Background for Change	2• <u>∧</u> • ≡ ≈ -≉ ×	E Ξ 温 モ ベ ス ズ ベ ロ H 我 ク ぐ る ■・Ω	
Background for Change	2• <u>∧</u> • <u>≡</u> (≈ -≈ ×	E 差 温 ゆ ペ ス オ ベ 留 所 乳 ラ ぐ る 目・Ω	
Background for Change Enter text.		開 開 圏 ゆ ゆ ち オ ー 目 戸 3 つ 0 δ 目・Ω	

Figure 44. Precise Scope and Background for Change



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

2.5.2. Present and Proposed Changes

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

Figure 45. Proposed Changes

Product Selection Pending X	Precise Scope and Background for Change [©]	>
Type(s) of Change(s) Pending		^
Procedural Information Pending X	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. esent/Proposed
Proposed Changes Pending	Comparison of the second	
Finalisation Pending		
	Sine Wilfele Cand Doort	

2.5.2.1. Present and Proposed Text Changes

Figure 46. Present and Proposed Changes

Type(s) of Change(s)		Present and Proposed Changes				^
Procedural Information	6	Please add a Present and Proposed change for ea check if structured product data needs to be upd		A product area will be recommended based on your s	cope selection. In addition	to free text / Organisation changes, please Q. Add Present/Proposed
Proposed Changes	1	□ Product MA Number(s) ↑	Scope(s)	Recommended Change(s)		Proposed Change(s)
Pending 📓		There are no records to display.				
Finalisation						
		Other Applications $\ensuremath{\mathbb{O}}$				>
	s	ave Validate Cancel Export				

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

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



Figure 47. Present and Proposed Values

	Present and P	Proposed Value	e(s)						E KP 18/09/	22 Quality Grouping	take2 / VAR/22/65	i0 😃 Last Save
resent and Propos	ed Value(s)	selected Scope(s)	Selected Medicin	al Product(s)								
Present *						_	Proposed *					
Enter text							Enter text					
I Font	• Size • B	I <u>U</u> <u>2</u> - <u>E</u>	. = =	= = = = =	∎ २ः ् x, ।	0	I Font	• Size • B	I <u>U</u> <i>L</i> - <u>A</u>	• = = = •= •	E 10 E E E E	ବି ବି ସ
Organisation Del	ails											
Organisation Def Organisation N ot Selectable ↑	organisation N ame (Present O rganisation)	Organisation Lo cation (Present Organisation)		Full address (Pr esent Organisat ion)			Organisation N ame (Proposed Organisation)	Organisation Lo cation (Propose d Organisation)		Full address (Pr oposed Organis ation)	Parent Organis ation ID (Propo sed Organisatio n)	
Organisation N	Organisation N ame (Present O	cation (Present Organisation)	(Present Organi	esent Organisat	ation ID (Prese nt Organisatio n)	esent Organisat ion) 17/07/2022 22:0	ame (Proposed Organisation)	cation (Propose d Organisation)	(Proposed Orga	oposed Organis	ation ID (Propo sed Organisatio n) European Medicin	oposed Organ ation)

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

Figure 48. Present and Proposed Values - Toolbar Options

esent *	Proposed *
Change 1 relates to the update of this and that.	Change 1 relates to the update of this and that.
Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and hat.	Change 1 relates to the update of this and that loads of text and images. Change 1 relates to the update of this and that. Change relates to the update of this and that.
	Present Okargo + Present and Proposed Value(s) 🗁 01/00/03/ank (source of a Value San and a Value San and a Value San and a Value San a Value S
	Neural and Preprint Table(s) Second Travity: Second Travity(s)
	hare" "A state" to an
	The second se
	spanskas i paparakas i papara
	the first interaction of the second sec
	🗋 le sue es 1611 ofestie a lanç la latere de después ses soulhes operantes adhes de registrater is adq, la latere
Change 2 relates to the update of this and that.	Change 2 relates to the update of this and that.
Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and hat	Change 1 relates to the update of this and that. Change 1 relates to the update of this and thes. Change 1 relates to the update of and that.
න් Segoe UI • 9 • 🖪 / U 🖉 • A • 🚍 🚍 +≣ +≣ # 📰 🚍 = = වා වා x, 💽 🍸	

Please note: There is currently an issue with the design which means that it is not possible to save the changes constantly in this section. In order not to lose any changes, ensure that you either **save the free text in the** Present and Proposed fields before **selecting the organisations that are impacted from OMS**. Changes added to the Present and Proposed fields **will be lost** if you enter



these first and then add an organisation details using the + Add button to select the Present and Proposed organisations without saving.

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

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

Figure 49. Selection of Scope and Medicinal Product

Pres	resent and Proposed Value(s) Selected Scope(s) Selected Medicinal Product(s) Present * Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and that.	Selected Medicinal Product(s)			
	Present *				Proposed *
	Change 1 relates to the update of the		to the update of this and that. Change 1 relates to the update of this an	1	Change 1 relates to the update of this and that. Change 1 relates to the update of this and that loads of text and images. relates to the update of this and that.

2. In the 'Selected Scopes' tab you can see all the scopes you selected earlier in section Type(s) of Change(s). Select the one(s) that you would like to link to a specific product/presentation you selected in the Product selection. If all changes concern all products/presentations, simply select all of them. You can repeat this step to link the changes in present and proposed to a particular scope/product combination.

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

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



Figure 50. Selection of Scope and Identifier

Present	and Proposed Value(s) Selected Scope(s) Select	ed Medicinal Product(s)		
Colum	n visibility 🐱			Filter
•	Identifier	Scope	Recommended Change(s)	Description
	B.II.b.1.e - Variation Type IB - 1	B.II.b.1.e Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products	Text / Org. Changes	B.I.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing stefe for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(3) take place. except Patch-relates. batch control, pirmary and secondary packaging, for nonsterile medicinal products
	B.II.b.2.a - Variation Type IA - 1	B.II.b.2.a Replacement or addition of a site where batch control/testing takes place	Medical Device	B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
۵	B.II.b.2.a - Variation Type IA - 2	B.I.I.b.2.a Replacement or addition of a site where batch control/testing takes place	Medical Device	B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
	B.II.g.I.a - Variation Type II - 1	B.II.g.1.a One or more unit operations in the manufacturing process of the finished product including the resulting in- process controls and/or text procedures	Text / Org. Changes	B.II.g.1.a - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Introduction of a new design pasce or extension of an approved design space for the finished product, concerning - One or more unit operations in the manufacturing process of the finished product including the resulting in-process controls and/or test procedures

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

NOTE:

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

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

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



Figure 51. Selection of Products and MA

	Selected Medicinal Product(s)			
Column visibility 🐱			File	er C
Troduct Name	MRP / CP Number	MA Number	Authorisation Country	PMS Id
			European Union	
0			European Union	
howing 1 to 2 of 2 entries 1 row selected				
elected Packaged Medicinal Product(s)				
Column visibility ~				_
column visionity •				er C
TMA Number	MRP / CP Number	PMS ID	Pack Size	er Authorisat Status
	MRP / CP Number	PMS ID		Authorisat
MA Number	MRP / CP Number			Authorisat Status
Ø MA Number	MRP / CP Number			Authorisat Status Valid
2 MA Number 22	MRP / CP Number			Authorisat Status Valid Valid

If you have multiple changes/scopes that impact only part of the products selected, repeat this change to indicate the changes linked to those scopes. To repeat the step click on Add Present/Proposed. The selected scopes and products will be shown and can be edited

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

Figure 52. Add Present/Proposed Changes

Present and Proposed Changes					^
Please add a Present and Proposed change for each Scope a product data needs to be updated.	ind Medicinal Product combination. A product area will be recomme	ended based on your scope selection. In add	dition to free text / 0	Organisation changes, plea	ise check if structured Add Present/Proposed
Product MA Number(s) ↑	Scope(s) B.II.b.2.a - Variation Type IA - 1,B.II.b.2.a - Variation Type I A - 2	Recommended Change(s) Medical Device		Proposed Change(s)	0

2.5.2.3. Organisation Details

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

Please note: There is currently an issue with the design which means that it is not possible to save the changes constantly in this section. In order not to lose any changes, ideally to ensure that you **select organisations that are impacted from OMS as the first step**. Changes added to the Present and Proposed fields may **be lost** if you enter these first and then add an organisation details using the **+** Add button to select the Present and Proposed organisations.

Additionally, we are working on an improved design for the whole 'Present and Proposed' section, including the part where the organisations are selected to improve the user experience. These changes



will be implemented in an incremental way and it is planned that the improvements will be available in the form before the end of Q3 2024.

- In the Proposed Changes page- Present and Proposed Value(s) subsection, if you need to add an organisation, please note that it is very important to save the changes done in the free text fields before you **do this step first** in order not to lose any changes, click on + Add button to select the Present and Proposed organisations.
- 2. If the change does not concern any organisations, please tick the box to declare that this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder.

NOTE: this tick box will prevent saving the text in the free text fields and combining the scope and presentation. It must be ticked first!

Figure 53. Present and Proposed Value(s)

\mathbf{O}	ompleted 🕫 posed Changes > Present and Proposed Value(s)	
8	Present and Proposed Value(s) Selected Scope(s) Selected Medicinal Product(s)	
ぷ	Present * Proposed *	
	Enter text.	
Ì		
Ø		
\otimes	Do this step first	
	Organisation Na Organisation Lo Organisation Id Full address (Pr Parent Organisation Modified On (Pr Organisation Na Organisation Lo Organisation Id Full address (Pr Into ID (Procee Modified On (Pr Organisation Na Organisation Id Full address (Pr Into ID (Proceed Organisation address (Pr Into ID (Proceed Organisation) address (Pr Into ID (Proceed	
	Ves Catalent Indiana L LOC-100023094 ORG-100016312 1300 South Patter Catalent Indiana L 18/07/2022 01:0 Image: Company of the second	
	In case no OMS selection is done, I declare this change does not effect organisations unless the organisation is being deleted	
	Save Close	

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



Figure 54. Proposed Changes - Add/Edit Organisation

٢	Pending X Proposed Changes > View/Propose Changes > Add / Edit Org	Variation
Ô	Organisation Not Selectable	
ズ	Present Organisation	
ं	E-Mail (Present Org) Telephone (Present Org)	
\otimes	D-U-N-S number (Present Org) 🛈	
	Proposed Organisation *	

4. In the Select Present Organisation, use the search to find the organisation from OMS. You can only select one organisation. It is possible to toggle between 'active' and 'inactive' organisations (organisation/location status is retrieved from OMS).



Figure 55. Select Present Organisation

Select Present Organisation	>
i≣ All Inactive Locations -	٩
All Active Locations 4 ApS All Inactive Locations	INACTIVE
	INACTIVE
[INACTIVE]	INACTIVE
[INACTIVE] e Limited I	INACTIVE
[INACTIVE]	INACTIVE
[[INACTIVE] [INACTIVE
< 1 2 3 4 5 6 7 8 500 >	
	Select Cancel Remove value

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

Figure 56. Organisation Not Selectable

Drganis	ation Not Selectable ①	
	Organisation Not Selectable	
Present Or	The organisation is not selectable as 1) the organisation no longer exists, or 2) there is a	
	change in organisation name which does not affect the address	



Figure 57. Data of Not Selectable Organisation

Organisation Not Selectable ①	
Organisation Name *	City/Locality/Town/Village *
Address Line 1 *	Postcode
Address Line 2	State
Address Line 3	County
Address Line 4	Country *

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

Figure 58. Proposed Organisation

Ì	Pending ∑ Proposed Changes > View/Propose Changes > Add / Edit Org	Ē
<i>8</i> 6	☑ Organisation Not Selectable ①	
ぷ	Organisation Name *	City/Locality/Town/Village *
Ē	Address Line 2	State
ं	Address Line 3	County
Ø	Address Line 4	Country *
 &	Proposed Organisation *	
	Save Close	

8. Select the organisation and press on the Select button.



9. When present (where relevant) and proposed organisations have been selected, press the Save button to return to the Present and Proposed section to add the textual changes.

Figure 59. Present and Proposed Section

osed Changes > View/Propose Changes > A	dd / Edit Org	ĉ r
□ Organisation Not Selectable ①		
Present Organisation	Org ID	LOC ID
European Medicines Agency	× Q ORG-100013412	LOC-100020260
	Address	Modified On
	P. O. Box 71010	13/05/2024 12:05
	Amsterdam 1008 BA Netherlands	Status *
		Active
E-Mail (Present Org)	Telephone (Present Org)	
D-U-N-S number (Present Org) 🕕		
Proposed Organisation *	Org ID	LOC ID
European Medicines Agency	ORG-100013412	LOC-100020264
	Address	Modified On
	Domenico Scarlattilaan 6	23/05/2024 15:05
	Amsterdam 1083 HS	
	Netherlands	
E-Mail (Proposed Org)	Telephone (Proposed Org)	
D-U-N-S number (Proposed Org) 🛈		

Save Close

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



Figure 60. Present and Proposed Value(s)

Preser	nt and Propos	ed Value(s)	Selected Scope(s)	Selected Medi	cinal Product(s)									
Pr	esent *							Proposed *						
	Enter text							Enter text						
	I Font	- Size -	B I ∐ ∠	<u>∧</u> • ≡ ;= -=	+= n ≡ Ξ ;	≣ ® %, , ,		I Font	• Size •	BIU 🖉	• <u>A</u> • = = =	= n = 3	E = @ @ =	
	janisation N	Organisation ame (Presen	t O cation (Preser	nt (Present Organ		nt Organisatio		ame (Proposed	cation (Propos	se (Proposed	Orga oposed Org		ropo Modified On (satio oposed Organ	
ot S No	Selectable ↑	rganisation) European Med es Agency	Organisation)		ion) 5 30 Churchill Place London E14 5EU United Kingdom		ion) 17/07/2022 22:0 7	Organisation) European Medicin es Agency	d Organisatior		ation) 3412 Orlyplein 24 3 DP Amster Netherlands		ation) edicin 12/09/2022 15 9	9:0
No		Austrian Ageno For Health And od Safety	ry LOC-100000001 I Fo	ORG-100003912	2 Beethovenstrasse		12/09/2022 14:0 9	Austrian Agency For Health And Fo od Safety	LOC-100000004	ORG-100003	3912 Traisengasse igittenau 121 enna Austria	00 Vi For Health Ar	ncy 12/09/2022 14 nd Fo 9	\$:0
	a case no OMS :	selection is done	I declare this change	i does not affect orga	anisations unless the or	ganisation is being d	leleted							
Save	Close on Details													+ 4
ganisatio	Organisation Name (Present	Location	Organisation Full add Id (Present (Present Organisation) Organisa	organisation	Modified On E-Mail (Present (Present Organisation) Org)	t (Present	number Name (Present (Propos	sation Organisation Location sed (Proposed sation) Organisation)	Organisation F Id (Proposed (Organisation) C	Proposed ID (nnt enisation Proposed anisation) Medified O (Proposed Organisati	(Proposed (P	tephone D-U-N-S roposed number rg) Org)	+ 4
- 20 - 20	Organisation Name (Present	Location (Present	Id (Present (Present	Organisation ID (Present	(Present (Present	t (Present	number Name (Present (Propos	Location sed (Proposed	1d (Proposed (Proposed ID (Anisation Proposed (Proposed	(Proposed (P on) Org) Or	roposed (Proposed	+ 4
ganisatio	Organisation Name (Present	Location (Present	Id (Present (Present	Organisation ID (Present	(Present (Present	t (Present	number Name (Present (Propos Org) Organis Adec	Location sed (Proposed sation) Organisation)	Id (Proposed (Organisation) 0	Proposed ID (erm 13/05/2024	(Proposed (P on) Org) Or	roposed (Proposed	

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

Figure 61. Pop-Up showing details inserted




2.5.3.Add Package to an Existing Product - Updated

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 "Proposed Changes" section, then choose "Present and Proposed Changes".
- 2. Subsequently, click on "Add Present/Proposed" to proceed with this action.

OR + IAM Noel Diamant +
pplication for variation to a marketing authorisation VAR/23/972 ≟, Last Saved : 06/11/2023 14:22
>
^
n changen, please check lif Add Preset #/Proposed
Add Mesent/Proposed

- 5. Fill in details in 'Present and Proposed Value(s)' tab
- 6. Select **1 scope** (for example B.II.e.5.a)
- 7. Select the tab "Selected Medicinal Product(s)."
- 8. 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.

£			Variatio	n Form Human / Version: 1.0.1.14 / Application for v	ariation to a marketing authorisatio
Changes > Present and Proposed Value	e(s)			🖻 👘 VAR/24/1513	≟ Last Saved : 17/07/2024 13:1
esent and Proposed Value(s) Selected Scope(s) Selected Medicinal Product(s)				
Column visibility 🐱				Filter	٩
Product Name	MRP / CP Number	MA Number		Authorisation Country	PMS Id
CARCENTER STATES	EMEA/H/C/00JJ95	EU/1/2		European Union	600006-70961
nowing 1 to 1 of 1 entries 1 row selected					
elected Packaged Medicinal Product(s) Column visibility ~ Refresh 2				Filter	Q Add Package
TMA Nubber	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status
EU/1/22/1648/001	EMEA/H/C/005095	8140001	1 bag	Packaging: bag (EVA), Package size: 1 bag, Content: 30 ml or 70 ml	Valid
ving 1 entries 1 row selected					

- 9. Click the option "add package", this will open a pop up window to include the details for the new pack size
- 10. 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				×	
	Paren	t Medicinal Product *		v	р 19 5 6	
ं	MAN	umber *	Pack Size *			
S						
	Submit	l.				
	C THA Number	HRP / CP Number	PHS 10	Pack Size	Authorisation Status	
			No data available in table			
	Silvering 2 entries					
l Package						>
	Parent Medicinal I	Product *				
					~	
	CARV ************************************	rsion for	infusion Pack Si	ze *	⊳	
	Submit					

11. 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

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

Add Package				
\$	Parent Medicinal Product *	Arsion for infusion		~
	MA Number * EU/1/22/1648/002		Pack Size * 1 bag (content 15 ml)	
	Submit			

- 13. You can now see the newly added pack size in the list of packaged medicinal products.
- 14. 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.

	↑Product Name	MRP / CP Number	MA Number	Authorisatio	n Country	PMS Id
	C s dispersion for infusion	EMEA/H/C/005095	EU/1/22/1040	European Uni	on	e
G						
Selecte	d Packaged Medicinal Product(s)					_
	Column visibility 🗸 Refresh 💋			Filter		Q Add Pa
	↑MA Number	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status
	EU/1/22/1648/001	EMEA/H/C/00	8140001	1 bag	Packaqing: baq	Valid

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

9	
EUROPEAN MEDICINES	

\mathcal{O}_{Θ}	Product Selection	Products c	concerned by this a	pplication (1)										
	Pending 🚡	Col	lumn visibility 👻 🗄	Show 10 rows 👻 🕴	Refresh 🟿			As	sociate MRP Nr.	Search			٩	+ Add Product
ぷ	Type(s) of Change(s) 												MRP	Nr. of
	Pending 🛛 🛣		Full ↑ ^{Name}	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.①	MRP / CP Nr.	р	MS ID	MP ID	Variation Nr.	Selected Packages
	Procedural Information		1			ß								
	Pending 🛛 🛣	~		Dispersion for infusion	Ciltacabtagene autoleucel	European Union								1/2
\odot	Proposed Changes		ţ.											
	Pending 🔀		Selected Package	d Medicinal Produc	t(s)						Search			
\bigotimes	Finalisation Pending 🛛 🛣		Full Name		Pack Size	Pac	kage Description	MA Numbe	er	Package ID		Authorisa Status	ition	
			n		1 bag	Pa ka 30		vac nt: EU/1/22/	/1648/001			Valid		
				$2 \times 10^{6} - 1 \times 10^{6}$	1 bag (content :	15 ml)		EU/1/22/	/1648/002			Pending		

- 17. If you have more medicinal products for which you wish to add a pack size, you simply repeat the steps above.
- 18. When the pdf is generated, you can see the newly added pack size details, generated in section2 (like you would have entered them manually in interactive pdf eAF in section 2).

2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

Active Substance		
Oci u u i î î î î î î î î î î î î î î î î î î		
A Number(s) ⁸ Full name ²¹	MA Holder name Mem	ber state Pharmaceutical Form 22
A Number(s) ⁸ Full name ²¹	MA Holder name Mem Europ Unior	bean Powder and solvent for solution for

19. 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)	Keep wder and solvent for solution for injection all packages listed in section 2 for the product					
	Present ^{9,10}	Proposed ^{9,10}				
Text	details on the existing presentations	new presentation (multipack) Add details to present and proposed fields as per normal				
	Present ^{9,10}	Proposed ^{9,10}				
	EU/1/1: 76/0XX					
		Package These fields contain the information from the M information from the M number and Pack size fields the pop up window - MA number: EU/1/10/0016/0XX These fields contain the information from the M number and Pack size fields the pop up window - Description: 1 + 1 (new multipack) These fields contain the information from the M number and Pack size fields the pop up window				
	I declare this var ⊠ address change, Authorisation Ho	ation does NOT result in any changes in manufacturers (i.e. name/ addition or replacement of manufacturing site) or the Marketing Ider				



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.

	Product Li Manageme	fecycle ent Portal	A Home Pr	oducta Management Service + ePL + Application For	ns • Forum SPOR • IAM	Noel Diamant +
Ì	Pending 😨 Proposed Changes			Variation Form	Human / Version: J.110 / Application for variation to Demo test ND / VAR/23/972 🛓 Last S	
<i>8</i> 9	Product Selection Pending	Precise Scope and Background for Cha	nge ©			×
ж,	Type(s) of Change(s) Pending	Present and Proposed Changes				^
	Procedural Information Pending	Please add a Present and Proposed change for ead structured product data needs to be updated. Proposed Change		area will be recommended based on your acope selection. In addit		if g/Proposed
Ċ	Proposed Changes	Product MA Number(s) †	Scope(s)	Recommended Change(s)	Proposed Change(s)	naa Present/Proposed
ø	Finalisation	There are no records to display.				
		Other Applications ①		_		>

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

Presen	t and Proposed Value(s) Selected Scope	(s) Selected Medicinal Product(s)		
	Column visibility 🐱			Filter
	Identifier	↑Scope	Recommended Change(s)	Description
۵	B.II.e.5.a.1 - Variation Type IAIN - 1	B.II.e.5.a.1 Change within the range of the currently approved pack sizes	Text / Org. Changes	B.II.e.5.a.1 - QUALITY CHANGES - FINISI PRODUCT - Container closure system - Cl in pack size of the finished product - Char the number of units (e.g. tablets, ampoul etc.) in a pack - Change within the range currently approved pack sizes
	B.II.e.5.a.1 - Variation Type IAIN - 2	B.II.e.5.a.1 Change within the range of the currently approved pack sizes	Text / Org. Changes	B.II.e.5.a.1 - QUALITY CHANGES - FINISI PRODUCT - Container closure system - C1 in pack size of the finished product - Chan the number of units (e.g. tablets, ampoul etc.) in a pack - Change within the range currently approved pack sizes
	C.I.6.a - Variation Type II - 1	C.I.6.a Addition of a new therapeutic indication or modification of an approved one	Pharmacotherapeutic Group (ATC)	C.I.6.a - SAFETY, EFFICACY, PHARMACOUGLANCE CHANGES - HUMA VETERINARY MEDICINAL, PRODUCTS - Change(s) to therapeutic indication (s) - Addition of a na pervoved one modification of an approved one

T.



- 5. Select the tab "Selected Medicinal Product(s)."
- 6. Following the updated design, it is recommended to select the medicinal product in the pop-up window instead of selecting it on the list to avoid selecting different medicinal product from the list and from the pop up; the currently approved presentations (pack sizes) are listed under the section packaged medicinal product.

sent and Proposed Value(s) Selected Scope(s)	Selected Medicinal Product(5)			Filter	٩		
☐ ↑Product Name	MRP / CP Number	MA Number	Authorisation	Country	PMS Id		
tion for	EMEA/H/C/004587	EU/1/19/1364	European Unio	n			
INOCELVA SO OTHES powder for solution for injection							
wing 1 to 2 of 2 entries 1 row selected							
ected Packaged Medicinal Product(s)							
olumn visibility 🗸 Refresh 💋			Filter		Q Add Package		
☐ ↑MA Number	MRP / CP Number	Package ID	Pack Size	Package Description	Authorisation Status		
EU/1/19/1364/002	EMEA/H/C/004587		1 vial	Packaging: vial (glass), Package size: 1 vial	Valid - Transferred marketing authorisation		
	EMEA/H/C/004587)1	4 (4 × 1) vials (multipack)	Packaging: vial (glass) , Package	Valid		
EU/1/19/1364/003				size: 4 (4 x 1) vials (multipack)			

- 7. 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
- 8. Select the 'Parent Medicinal Product'. If you have more than 1 medicinal product and you wish to add a package to each medicinal product, you will need to repeat this step. It is not possible to select multiple medicinal products at one go.
- 9. 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.

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

	cinal Product *		۹	
MA Number				Search Q
	Choose one record and click Select to continue	2		
	✓ 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 60000001923
Submit	INTEGRILIN 2 mg/ml solution for injection	EMEA/H/C/000230	EU/1/99/109	European Union 60000001924
				Select Cancel Remove value

- 11. You can now see the newly added pack size in the list of packaged medicinal products.
- 12. If you wish to delete the new draft package, you can click delete and repeat the step to add it again

☐ ↑Pr	roduct Name	MRP / CP Number	MA Number	Authorisation Count	יז	PMS Id
	IUCEIVA 100 Units powder for solution for injection	EMEA/H/C/004587	EU/1/19/1364	European Union		
a ,	UCEIVA S0 Units powder for solution for injection	EMEA/H/C/004587	EU/1/19/1364	European Union		
wing I	to 2 of 2 entries I row selected					
ected Pa	ckaged Hedicinal Product(s)					
olumn visi	bilty ~ Refresh Ø				Filter	Q Add Pack
	4HA Number	HRP / 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 \times 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 (4×1) 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

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



Present and Proposed Value(s) Selected Scope(s) Selected Medicinal Pr	aduct(s)		
Column sublity +			Filter Q
Identifier	15cope	Recommended Change(s)	Description
B.II.e.S.a.1 - Variation Type IAUN - 1	$B. \mathrm{II.e.} 5.a.1$ Change within the range of the currently approved pack sizes	:Text / Org. Changes	B.IT.e.S.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
B.I.L.e.S.a.1 - Variation Type IAIN - 2	B.II.e.5.a.1 Change within the range of the currently approved pack sizes	Test / Org. Changes	B.II.e.S.e.1 - QUALITY CHANGES - PINISHED PRODUCT - Container closure system - Change in pack sizes 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.L.6.a - Variation Type II - 1	C.1.6.a Addition of a new therapeutic indication or modification of an approved o	ne Pharmacotheriepeutic Group (ATC)	C.1.6.# - SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUNAN AND VETERBARY HEDICINAL PRODUCTS - Change(a) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one
howing 1 to 3 of 3 entries I row selected			
Save Close			
Add Package			×
	Parent Medicinal Product *		
Present	NUCEIVA 100 Units powder for solution for injection	٣	
	MA Number *	Pack Size "	
Colume	EU/1/19/1364/006	2 x 1 vial (multipack)	
			945 Id
8	_		000000
0	Sthmit		000000
Showing 1 to 2 of 2 entries 1 row selected			
Selected Packaged Hedicinal Product(a)			
Column visibility 🐱 Refresh 🝠			Fiber Q, Add Pe
TMA Number	HBD / CP Number Package	e ID Pack Size	Package Description Authorisation Status
		1 vial	Packaging: vial (glass), Package Valid- size: 1 vial meeksing authorisation
Showing 1 entries 1 row selected			
			,

Ø	Product Selection Pending	Pro		ncerned by this a	show 10 rows -	Refresh 💋			Ass	ociate MRP Nr. S	Search			٩	+ Add Product
ぷ	Type(s) of Change(s) Pending ∑			Full ↑ ^{Name}	Authorised Dose Form	Active Substance	Authorisatior Country	n MA Holder	ma nr.@	MRP / CP Nr.		PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
() ()	Procedural Information Pending 🔀 Proposed Changes		^		Dispersion for infusion	Ciltacabtagene autoleucel	↓ European Union					_			1/2
CI.	Pending X		s	elected Package	d Medicinal Produ	uct(s)						Search			
\otimes	Pending 🔀			Full Name		Pack Size	Pa	ckage Description	MA Number		Package I	D	Authoris Status	sation	
				n		1 bag	k	2 2 6 mm or 70 mm	יac nt: EU/1/22/3	.648/001			Valid		
					$.2 \times 10^{6} - 1 \times$	1 io 1 bag (content	15 ml)		EU/1/22/3	648/002			Pendin	ıg	

- 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 section2 (like you would have entered them manually in interactive pdf eAF in section 2).



2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

Active Substance			
Oc'galfa			
Number(s) ⁸ Full name ²¹	MA Holder na	me Member sta	te Pharmaceutical Form 22
Vumber(s) ⁸ Full name ²¹	MA Holder na	me Member sta European Union	te Pharmaceutical Form ²² Powder and solvent for solution for injection

17. 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 wder and solvent for solution for inje	all packages listed in section 2 for the product
	Present ^{9,10}	Proposed 9,10
Text	details on the existing presentations	new presentation (multipack) Add details to present an proposed fields as per normal
	Present ^{9,10}	Proposed 9,10
	EU/1/1{ 76/0XX	
		Package These fields - MA number: EU/1/10006/0XX number and Pa the pop u - Description: 1 + 1 (new multipack)
		iation does NOT result in any changes in manufacturers (i.e. name/ , addition or replacement of manufacturing site) or the Marketing Ilder

2.5.3.3. Multiple change

2.5.3.3.1. Duplicating the Present and Proposed fields

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



2.5.3.3.2. Linking of the organisations to the text changes

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

2.5.3.4. Structured changes

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

2.5.3.5. Medical Device(s)

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

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

Figure 62. Medical Device Box

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

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

Figure 63. Add Present/Proposed Changes

Present and Proposed	Changes						^
Please add a Present and Pro updated.	cosed change for each Scope and Medicin	al Product combination. A product area will b	e recommended based on your scope se	election. In addition to free text / Organ	nisation changes,		data needs to be Add Present/Proposed
Product MA Number(s)↑	Scope(s)	Recommo	ended Change(s)		Proposed Change(s)	
There are no records to dis	play.						



3. Select the scope and the medicinal product/presentations

Figure 64. Selected Scope(s)

<i>C</i> _O	Present and Proposed Value(s) Selected Scope(s) Se	lected Medicinal Product(s)		
×	Column visibility 🐱			Filter Q
	Identifier	1 Scope	Recommended Change(s)	Description
	B.IV.1.a.1 - Variation Type IAIN - 1	B.IV.1.a.1 Device with CE marking	Medical Device	B.IV.1.a.1 - QUALTY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking
. 📀				
\otimes	Save Close Showing 1 to 1 of 1 entries			

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

Figure 65. Selection of relevant scope/product combination

Present and Proposed Changes					
Please add a Present and Proposed change for	or each Scope and Medicinal Product combination, A p	product area will be recommended based.	on your scope selection.	In addition to free text /	Organisation changes,
	or each Scope and Medicinal Product combination. A p Is to be updated.	Proposed Change	Search	In addition to free text /	Add Present/Propos
Please add a Present and Proposed change to please check if structured product data need Product MA Number(s) ↑			Search	Proposed Change	Add Present/Propos

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



Figure 66. Add Device

osed Changes > Pres	ent & Proposed Medical Device		
✓ Selected Scope(s)			
Medical Devices			
Present Values			
Device Name		Parent Medicinal Product	
		No data available in table	
		No data available in table	
Showing 0 to 0 of 0 entries			
			4
Proposed Values Ref	resh 🖉		Add Device Remove Association(s) Delete Devi
	Device Name	Parent Medicinal Product	
		No data available in table	
Showing 0 to 0 of 0 entries			
			<
Save Cancel Delete	Proposed Change		

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

Figure 67. Medical Device and Companion Diagnostic

Change to the de	asign or intended purpose of the device component, or introduction of a new device / device constituent part	
Device(s) identif	ication and classification	
Manufacturer of	the device	
Documentation t	o 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 (N		

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

Figure 68. Change Selection - Medical Device and Companion Diagnostic

Medical Device & Companion Diagnostic





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

Figure 69. Device(s) Identification and Classification

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

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

Figure	70.	Manufacturer	of	the	Device

Manufacturer of the device			^
Function *			
Manufacturer •			
Title *	First Name *	Last Name *	-
Telephone	E-Mail	u	

10. Proceed to fill in the rest of the sections

Figure 71. Upload of Documentation

Documentation to confirm compliance to the Medical Device Regulation (EU) 2017/745 and/or to the in vitro diagnostic Medical Device Regulation (EU) 2017/746
Does this application include a Manufacturer's EU declaration of conformity, an EU certificate issued by a Notified Body or a Notified Body opinion, if applicable?
Please note, the above mentioned documents (as applicable) should be provided in module 3.2.R of the EU-CTD.

11. Notified body is also now selected from OMS



Figure 72. Notified Body

Notified Body (NB)			^
Notified Body Number *]		
Name of the Notified Body *			
۹			
Title *	First Name *	Last Name *	
Telephone	E-Mail		

2.5.3.6. ATC Code change

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

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

Figure 73. Present and Proposed Changes

Present and Proposed Changes					^
Please add a Present and Proposed change for please check if structured product data needs	each Scope and Medicinal Product combination. A to be updated.	product area will be recommended based on your Proposed Change	scope selection. In addit		inisation changes, dd Present/Proposed
□ Product MA Number(s) ↑	Scope(s) B.IV.1.a.1 - Variation Type IAIN - 1	Proposed Change Genetically Modified Organisms Medical Device Pharmacotherapeutic Group (ATC) Pharmacovisigilance System Master File	P	roposed Change(s)	٥

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



Figure 74. ACT Code Change

✓ Selected :	Scope(s)		
Pharmaco	therapeutic Group (ATC)		
Present Valu	ies		
	[†] MA number	Product Name	
\sim	EU/1/21/1531	Evrysdi 0.75 mg/ml - Powder for oral solution	
			~
Droposed Values			
Proposed Values ATC Code ↑		Application for ATC code has been made	
ATC Code ↑	nde to display	Application for ATC code has been made	
	ords to display.	Application for ATC code has been made	

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

Figure 75. Selection of ATC Code

Select ATC Code	×
FHIR Product ATC Code ATC Code If you not accord to the second state of the an application for ATC code has been made	Lunch Tochp recold

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

2.5.3.7. Pharmacovigilance System Master File

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



Figure	76	Pharmacovigilanc	e Sv	stem	Master	File
Iguie	/0.	Filarmacovignanc	-c - 3 y	Stem	riastei	1116

Present Values					
MA Number	Product Name	PSMF Code	PSMF Organization	The Pharmacovigilance system mast registered in Article 57 database	er file location has been
Showing 1 to 1 of 1 entries					~ 1
Proposed Values					
IF Organisation *		q	PSMF Code *		
IF Organisation *		٩			
IF Organisation *		٩			
IF Organisation *		٩			
F Organisation *		q			
F Organisation =		q			
F Organisation *		<u> </u>			
F Organisation =		<u> </u>			
	ster file location has been registered in Article 53				
The Pharmacovigilance system ma		7 database ation form, a Qualified person Respo	nsible for Pharmacovigilance 'resides' in	1 the place where he/she makes his/her home, w	here he/she lives, can be traced

Add the PSMF Organisation from the magnifying glass \mathbf{Q} and the PSMF Code

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

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

2.5.3.8. Genetically Modified Organisms

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



Figure 77. Genetically Modified Organisms Code

Genetically Modified C	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			« 1)
Proposed Values			
s the medicinal product contain GMOs? *			
es	~		
s the product comply with Directive 200	1/18/EC? *		
es	*		
Attach a copy of any written consent(s) of	of the competent authorities to the deliberate release into the environment of th	he GMOs for research and development purposes where provided for	by Part B of the above-mentioned Directive (Annex 5

2. Reply to the GMO-related enquiries

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

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

2.5.4. Other applications

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

For Centralised procedure, you should be able to find related procedure numbers from the pregenerated list of procedures which is opened by clicking the Select EMA Procedure button. If the procedure you wish to add is not available, please use the free text field opened by clicking the Add button



Figure 78. Selection of EMA Procedure

Other Applications	^
	Select EMA Procedure Add
Procedure Number ↑	
There are no records to display.	

2.6. Additional Information

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

Figure 79. Additional Information Section

23	Type(s) of Change(s)	Type IB and Type II variations - new indications - orphan medicinal product information	>
	Completed 🥑	Information relating to orphan market exclusivity	>
	Information	Type IB and Type II variations - Paediatric Requirements ${}^{\textcircled{0}}$	>
Ĩ	Proposed Changes	Type II variations - Extended data exclusivity / market protection	>
2	Additional Information	Save Validate Cancel Export	

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

1. To fill in this section select the relevant orphan designation using the magnifying glass ${f Q}$

Figure 80. Orphan Designation Procedure



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



Figure 81. Lookup Records

Lookup records							×
							٩
Choose one record and click Select to continue						-	
✓ Case Title ↑	Process Type	Status	Status Reason	Sub-Status	Case Subject	Submitted on	
	Application for Orphan Designation	Resolved	Completed	Positive			
	Application for Orphan Designation	Canceled	Withdrawn	Withdrawn			
						Select Cancel Ren	nove value

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

Figure 82. Selection of Procedure

Has orphan designation been applied for, for this new indication?	
O No @ Yes	
Select Orphan Designation Procedure	
EMA/OD/050/15	× Q
Ornhan designation procedure status	
O Pending Orphan Designation Granted Orphan Designation Refused Orphan Designation Withdrawn	
Orphan designation date	
10/08/2015	
Based on the criterion of "significant benefit":	
🔿 No 🍥 Yes	
Number in the Community Register of Orphan Medicinal Products	
EU/3/15/1532	
Attach copy of the Designation Decision	

2.6.2. Information relating to orphan market exclusivity

2.6.3. Type IB and Type II Variations – Paediatric Requirements

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



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

Type IB and Type II varia	ations - Paediatric Requirements ()			^
C Article 8 of the paediatric regu This application relates to a ne This application relates to pae A ticle 8 Procedure Type This application relates to a pr This application relates to a pr This application relates to a no A ticle 8 New Indication G is protected by a supplementa © This application relates to pae	on applies to this variation application since lation does not apply to this application sinc w indication for a paediatric use marketing diatric studies included in a paediatric invest diatric studies submitted according to Article evious/ongoing/parallel procedure which tri evious/ongoing/parallel procedure which tri evi indication for an authorised medicinal pro ry protection certificate under Regulation (E qualifies for the granting of the supplement diatric studies included in a paediatric invest diatric studies submitted according to Article	e. authorisation (PUMA). jagion plan. 143 or 46 of the paediatric re gered Article 8 requirement. duct which: C) No 469/2009. ary protection certificate. tigation plan			+ Ad
Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substa Decision	nce(s) for Agreed scope ↑	Agreed condition/indication
There are no records to displa	у.				
(Note: a copy of the PIP/Product Has this application been subject Has this application been subject O No @ Yes		atric Committee (PDCO) opin	nion and the Summary Report, is to be	included in Module 1.10)	bba +
The compliance document re	ference 🛧				
There are no records to displa	у.				

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

Figure 84. Selection of Paediatric Entitlement(s)

Sele	ect Paediatric Entitler	nent(s)			×
					Search Q
~	Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision Agreed scope $\ensuremath{\uparrow}$	Agreed condition/indication
< 1	2 3 4 5 6 7 8	173 >			
Se	ected records				
					Add Cancel

2. Add the entitlement



Figure 85. Addition of Paediatric Entitlement(s)

Select Paediatric Enti	tlement(s)			×
Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision Agreed scope ↑	105 Q Agreed condition/indication
Selected records				
				Add Cancel

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

Figure 86. Recap Table of Paediatric Entitlement(s)

Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision	Agreed scope ↑	Agreed condition/indication	
(Note: a copy of the PIP/Product-Spec Has this application been subject	ific Waiver decision including the paedi	atric Committee (PDCO) opinion and the	e Summary Report, is to be included in	Module 1.10)		

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

Figure 87. Creation of Compliance Document Reference Number

Create Compliance Document Reference Number	×	
Procedure Number		

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

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





2.7. Finalisation

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

Figure 89. Finalisation Process

\otimes	Pending X		
0	Product Selection	Annexed documents (where appropriate)	>
<i>с</i> ,	Type(s) of Change(s) Pending ∑	Declaration	>
	Procedural Information	Proof of payment	>
ч <u>—</u>)	Pending	Signatories	>
٢	Proposed Changes Pending X	Save Validate Cancel Export Finalise	
\otimes	Finalisation		

2.7.1. Annexed documents (where appropriate)

Figure 90. Annexed Documents

Annexed documents (where appropriate)	
The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable.	
Mock ups	
Specimens	
Summary of Product Characteristics	
Labelling	
List of all authorised presentations (Annex A)	
Package Leaflet	
Restrictions posed by Member States (Annex 127a)	
Annex II	



2.7.2. Declaration of the applicant

Figure 91. Declaration of the Applicant

		^			
	above. I declare that (Please tick appropriate declarations)				
baid in accordance with national requirements;					
for the changes concerned have been submitted;					
Chis 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) o r, in case of worksharing involving the EMA, to the relevant National Competent Authorities and/or RMS/ CMS (as applicable) and the EMA;					
🗧 * There are no other changes than these identified in this application (except for those addressed in other variations submitted in parallel));					
For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.					
Where applicable, all conditions as set for the variation(s) concerned are fulfilled;					
Changes implementation date	Changes implementation comment				
DD/MM/YYYY					
	paid in accordance with national requirements; d for the changes concerned have been submitted; sly in RMS and all CMSs (for products within the Mutual Recognition PI nal Competent Authorities and/or RMS/ CMS (as applicable) and the I oplication (except for those addressed in other variations submitted in ne MA: the MAs concerned belong to the same MAH. ncerned are fulfilled; Changes implementation date	for the changes concerned have been submitted; sly in RMS and all CMSs (for products within the Mutual Recognition Procedure and worksharing) or both to EMA and (Co-)Rapporteur (for products w nall Competent Authorities and/or RMS/ CMS (as applicable) and the EMA; pplication (except for those addressed in other variations submitted in parallel); ne MA: the MAs concerned belong to the same MAH, ncerned are fulfilled; Changes implementation date Changes implementation comment			

2.7.3. Proof of Payment

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

Figure 92. Proof of Payment

Have all relevant fees been prepaid to competent authorities? ① No ○ Yes (for the fees paid, attach proof of payment in Annex) Customer Purchase Order / Refer ence Number Address / Billing address ↑ Customer Account Number Full Address Telephone E-Mail	nt	^
Customer Purchase Order / Refer ence Number Address / Billing address ↑ Customer Account Number Full Address Telephone E-Mail		
European Medicines Agency Domenico Scarlattilaan 6 1083 HS A	Address / Billing address ↑ Customer Account Number Full Address Telephone	•

2.7.4.Signatories

Figure 93 – Signatories

Signatories			^
Main Signatory		dditional Signatory	
First Name *	Fi	irst Name	
	L		
Sumame *	s	urname	
	L		
Status(Job Title) *	S	tatus(Job Title)	_
	i l		
Date *	D	ate	
dd/mm/yyyy 🕲		dd/mm/yyyy E	Ð
□ For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the design on behalf of the design of the d	gnate	ed contacts as specified in section 2.4.3 in Part IA/Module 1 Application Form for each of the MAs concerned.	

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



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

If the user wishes **to include a signature in exported pdf**, this can be done using any external signature tool, for example Adobe signature or a more formal digital signature tool. An image of a signature can also be included in the exported pdf if preferred.



3. Exporting the form content to a PDF

3.1. *PDF Export*

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

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

Figure 94. Preparation of Export

P 18/09/22 Q	uality Grouping	g var/22/649			№ 18/09/2022 23:52:40 PM	
Export typically takes less	than a minute but can tak	e longer to complete, depending on the si	ze of your Application. You'll get an email to notify y	you when the process i	s complete and ready to download.	
Export Started						
Column visibility Sho	ow 10 rows				Search	Q Refresh
UMOdified On	Created On	Requestor	Status Reason	FHIR PDF	Validation XML	Export Message
19/09/2022 00:34: 20 AM	19/09/2022 00:34: 20 AM	Kristiina Puusaari	Active			
owing 1 to 1 of 1 entries						

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

Figure 95. Export Completed

2 18/09/22 0	Juality Groupin	Q VAR/22/649			№ 18/09/2022 23:52:40 PM		
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.							
control cypically takes les.	r chan a minute but can tak	e longer to complete, depending on the size.	or your Application. You'll get an email to notify	you when the process is	omprete and ready to download.		
			Completed				
			Download 🛓				
Column visibility Sh	ow 10 rows				Search	Q R	
U Modified On	Created On	Requestor	Status Reason	FHIR PDF	Validation XML	Export Messa	

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

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



Figure 96. Exported Form

✓ ▲ 8329a58e-d235-ed11-a81b-000d3aae5 18/09/2022 21:26 Adobe Acrobat D 734 KB	-0			
	✓ ♣ 8329a58e-d235-ed11-a81b-000d3aae5	18/09/2022 21:26	Adobe Acrobat D	734 KB

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

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

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

Figure 97. FHIR xml

ß	Attachments X	
	E- 💪 🗎 💪 🔟 💪	
М		
@<	Name C eAF.xml	
-	Name: eAF.xml	
	Modified: 18/09/2022 21:23:06 Size: 880.61 KB	
		Generated: 2022-09-18 07:23:01 (UT)
		TABLE OF CONTE
		1. APPLICA
		2. PRODUC 3. TYPES O
		4.a Type IB a



Figure 98. XML file - Document Tree



3.2. *PDF Requirements*

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



4. Support

4.1. The PLM Portal eAF Guidance materials

The updated PLM Portal home page contains links to various different guidance documents, videos and Q&A documents. You can follow the quick link to <u>eAF guidance page</u> from the eAF tile or you can access the main <u>PLM Portal Guidance and Support page</u> 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.

Product Lifecycle Management Portal		
H. Arte		
Electronic application forms (eAF) A secure online portal for managing electronic Application Forms.		
Create new eAF eAF list eAF guidance		
Quick links		
eAF news eAF release notes eAF FHIR XML release notes	> > >	
Privacy Guidance & Support EMA Service Desk Legal		

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. <u>Ask EMA</u> 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 <u>PLM Portal-eAF section of the EMA</u> <u>Service Desk portal</u>. 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 <u>Sign up for a new account or reset your login credentials</u>.

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

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

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

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

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



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



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 PLM Portal – eAF How to fill in the "Additional Information"			
	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		
*Raise this request on behalf of Kristiina Puusaari	× ×		
*Subject			
*Description			
* Problem area			
	Ψ		
*Urgency			
None	Ŧ		
Add attachments			
W Aud attachments			



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

	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	Web-user interface / Data / Access / FHIR XML / PDF export /
	Web-user interface / Data / Access / FHIR XML / PDF export /
Raise this request on behalf of Kristiina Puusaari	Web-user interface / Data / Access / FHIR XML / PDF export / Regulation / Other
Raise this request on behalf of	Web-user interface / Data / Access / FHIR XML / PDF export / Regulation / Other
Raise this request on behalf of Kristiina Puusaari Subject	Web-user interface / Data / Access / FHIR XML / PDF export / Regulation / Other
Raise this request on behalf of Kristiina Puusaari Subject	Web-user interface / Data / Access / FHIR XML / PDF export / Regulation / Other



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

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

4.4. The PLM Chatbot



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

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

Figure 101. PLM Chatbot

Product Lifecycle Management Portal			🛧 Home	Forum SPOR - IAM Sign in
Welcome to PLM I A secure online portal for managing electr Information (ePI) and authorised product collaboration with the European Medicines Sign In > Quick links	onic Application Forms, electronio data (PMS) in the European Unio		3	Hellol We are here to provide you information about the PLM Portal – eAF and the Type II programmes. Use the buttons, type directly in the chat, or type "restart" at any point to start over. Please choose one of the following topics: PLM Portal – eAF Post-authorisation Help
Public Register & O List O	Guidance & Support	گ	Ne	Aust now ar message