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Draft 1.3

# **Product Lifecycle Management Portal – Human Variations eAF**

# **Guide to navigation - Updated**

Version 1.3

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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			L		SPOR - IAM Forum Sign in
Electronic application forms (eAF) A secure online portal for managing electronic Application Forms.		Electronic product information (ePI) eff on the FLM Portal streamlines product information management, enhancing data accessibility, accuracy, and collaboration across the product lifecycle.		Product Management Ser Product Data Naragement User Interface (UT), offers se available in the Product Naragement Services (PMS) dat	amless access to product data
eAF guidance >		Published ePIs > ePI guidance >		PMS guidance >	
Quick links					
eAF news eAF release notes eAF FHIR XML release notes	>	efi news efi nelease notes	>	PMS news PMS release notes	>
Privacy Guidance & Support EMA Service Deak Legal © 1995-2024 European Medicines Agency					HMA
				и. - Полония и полно и пол - Полно и полно	

Figure 1 - Sign-in

## 2.1.2. How to create a new electronic Application Form

Users with an active EMA account and either with the eAF Applicant Manager or the eAF Applicant Coordinator role if they originate from the pharmaceutical industry or with the eAF Competent Authority User if they originate from a NCA can create a new Application Form. Please refer to the <u>PLM Portal -</u> <u>eAF quide 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	BROR - IAM Forum Eign in
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, reset your password, or recover your username using the EMA Account Management Portal. 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,

Product Lifecycle Management Portal	Electronic application forms - Electronic product in Electronic application forms New Application Form
Electronic application forms (eAF) A secure online portal for managing electronic Application Forms.	Electronic product information (ePI). PF on the PLM Portal streamlines product information management, enhancing data accessibility, accuracy, and collaboration across the product lifecycle.
Create new eAF eAF list eAF guidance >	Create new ePI ePI list Published ePIs > ePI guidance >

Figure 2 – New Application Form

3. Click on Create new eAF/New Application Form

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

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

In the 1. Select Application Details screen:

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

Home > Application Forms > Draft Applica	tion Form		
Select Application Details 2 Add Co-Auth	or		
Application Form Type *			Friendly Name *
Variation Form Human		~	
Reference MAH (j)*			
		Q	
Create & Next Cancel			
	51		

Figure 3 - Application Form Type

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

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

elect Application	Details 2 Add Co-A	Author						
Application Form	n Type *				Friendly	Name *		
Variation F	orm Human			~	Super	Pill 50mg Type II chang	e of AS manufactur	rer
Reference MAH	()*							
				٩				2
Create & Next	Cancel							
Create & Next	Cancel							
Create & Next		Colu	umn visibility 🗸 Refresh ,	😂 Download 🖿			٩	+ Create New Application
		Colu	umn visibility  v	😋 Download 🖥			٩	+ Create New Application
		Colu Application Form Type	umn visibility ~ Refresh , ^Reference MAH	Created By	Created On	Modified By (Last User)	Q Modified On (Access Date)	+ Create New Application
ft Deactivates	d Completed All	Application			Created On 07/05/2024 11:50		Modified On	Status Draft
ft Deactivates	d Completed All	Application Form Type Variation Form Human Variation	Reference MAH           European Medicines           Agency           European Medicines	Created By Kristiina Puusaari	07/05/2024 11:50 06/05/2024	<b>(Last User)</b> Kristiina Puusaari	Modified On (Access Date) 07/05/2024 14:06 07/05/2024	Status Draft C Edit Application Form
ft Deactivates	d Completed All	Application Form Type Variation Form Human	Agency	Created By	07/05/2024 11:50	(Last User)	Modified On (Access Date) 07/05/2024 14:06	Status Draft
ft Deactivates	d Completed All	Application Form Type Variation Form Human Variation	Reference MAH           European Medicines           Agency           European Medicines	Created By Kristiina Puusaari	07/05/2024 11:50 06/05/2024	<b>(Last User)</b> Kristiina Puusaari	Modified On (Access Date) 07/05/2024 14:06 07/05/2024	Status Draft C Edit Application Form

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

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

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



Application Form Type *	Lookup records			×
Variation Form Human			LOC-100020264	٩
Reference MAH <sup>(1)</sup> *	Choose one record and click Select to continue Corganisation Name	Full address	Organisation Id	Organisation Location
	European Medicines Agency	Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands	ORG-100013412	LOC-100020264
Create & Next				
			Select	Cancel Remove value

Figure 5 - Reference MAH

Click <u>Select</u> to select the correct MAH from the search results. After you have selected the MAH, it is still possible to change it at this point if you realise it is not the correct organisation/location. You can remove the organisation by clicking the X next to the magnifying glass. At this point, you can perform this search as many times as needed.

lication Form Type *		Friendly Nar	ne *	
ariation Form Human	×Q	WonderPil	Type IA parameter change	
erence MAH ①*				
uropean Medicines Agency	× Q			
Org ID		LOC ID		
ORG-100013412		LOC-10	10020264	
Address		Custor	ner Account Number	
Domenico Scarlattilaan 6		123456	7890	
Amsterdam 1083 HS Netherlands		Modifi	ed On	
			2024 11:01	
e & Next				
Application Forms > Draft Application Form				
Application Forms > Draft Application Form				
Application Forms > Draft Application Form				
Application Forms > Draft Application Form     Application Datalls     2 Add Co-Author			Friendly Name *	
Application Form > Draft Application Form  Application Details 2 Add Co-Author  Application Form Type =		×Q	Friendly Name *	
Application Forms > Draft Application Form  Application Details 2 Add Co-Author  Application Form Type  Variation Form Type		×Q	Friendly Name * Wonderpill S0mg Type II	
Application Form > Draft Application Form C Application Details 2 Add Co-Author  Application Form Type  Variation Form Human Reference MAH ①*				
Application Forms > Draft Application Form  Application Details 2 Add Co-Author  Application Form Type  Variation Form Type		× Q		
Application Forms > Draft Application Form  ct Application Details 2 Add Co-Author  Application Form Type * Variation Form Human Reference MAH ①* European Medicines Agency				
Application Forms > Draft Application Form  Ct Application Details  2 Add Co-Author  Application Form Type •  Variation Form Human  Reference MAH ①*  European Medicines Agency  Org ID			Wonderpill S0mg Type II	
Application Form > Draft Application Form  Ct Application Details 2 Add Co-Author  Application Form Type  Variation Form Human  Reference MAH @*  European Medicines Agency  Drg ID  DRG-100013412  Address			Wonderpill S0mg Type II LOC ID LOC-100020264	
Application Forms > Draft Application Form  t Application Details 2 Add Co-Author  publication Form Type *  Variation Form Human  Reference MAH @*  European Medicines Agency  brg ID  RG-100013412  uddress Domenico Scarlattilaan 6			Wonderpill S0mg Type II LOC ID LOC-100020264 Customer Account Number	
Application Form > Draft Application Form  Ct Application Details 2 Add Co-Author  Application Form Type  Variation Form Human  Reference MAH @*  European Medicines Agency  Drg ID  DRG-100013412  Address			Wonderpill S0mg Type II LOC ID LOC-100020264	
Application Forms > Draft Application Form     2 Add Co-Author      2 Add Co-Author      4 Application Porm Type      Variation Form Type      Variation Form Human  Reference MAH @*  European Medicines Agency  Org ID  DRG-100013412  Madress  Domenico Scarlatiliaan 6 Amsterdam 1083 HS			Wonderpill 50mg Type II LOC ID LOC-100020264 Customer Account Number 1234567890	
Application Forms > Draft Application Form     2 Add Co-Author      2 Add Co-Author      4 Application Porm Type      Variation Form Type      Variation Form Human  Reference MAH @*  European Medicines Agency  Org ID  DRG-100013412  Madress  Domenico Scarlatiliaan 6 Amsterdam 1083 HS			Wonderpill S0mg Type II LOC ID LOC-100020264 Customer Account Number 1234567890 Modified On	
Application Forms > Draft Application Form     2 Add Co-Author      2 Add Co-Author      4 Application Porm Type      Variation Form Type      Variation Form Human  Reference MAH @*  European Medicines Agency  Org ID  DRG-100013412  Madress  Domenico Scarlatiliaan 6 Amsterdam 1083 HS			Wonderpill 50mg Type II LOC ID LOC-100020264 Customer Account Number 1234567890	
Application Forms > Draft Application Form     2 Add Co-Author      2 Add Co-Author      4 Application Porm Type      Variation Form Type      Variation Form Human  Reference MAH @*  European Medicines Agency  Org ID  DRG-100013412  Madress  Domenico Scarlatiliaan 6 Amsterdam 1083 HS			Wonderpill S0mg Type II LOC ID LOC-100020264 Customer Account Number 1234567890 Modified On	
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 Scafattilaan 6 Amsterdam 1083 HS			Wonderpill S0mg Type II LOC ID LOC-100020264 Customer Account Number 1234567890 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:

Home Application Forms Draft Application Form

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.

p-authors added to this application				Add Co-au
Full Name	Contact Email	Role ↑	Role Status	
Kristiina Puusaari	Kristiina.Puusaari@ema.europa.eu	EMA Admin Assistant	Affiliated	0
ordinator(s) with implicit access to	this application			
ill Name	↑ Contact E-Mail	Role	Ro	le Status
		No data available in table		
				R.
revious Next Close				

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



From My Organisation Affiliate(s)	From Other Organisation(s) Column visibility v	Search Q
TFull Name	Role	E-Mail
	Applicant Manager	ema.europa.eu
Save Return Showing 1 to 1 of 1 entries		



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.



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

Figure 9 - Add Co-author

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

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

Application Friendly Name Form Id	Application Form Type	↑ <sub>Reference MAH</sub>	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
Application Forms Vew/Manage Co-Authorauthors added to this application	Y	Figure 10 - Vi	iew/Manage (	Co-author:	5		
	Y	Figure 10 - Vi	iew/Manage (	Co-authors	5		() Add Co-suther
	Contact E-Mail		iew/Manage (	Co-author:	S Role Status		() Add Ce-author
authors added to this application				Co-author:			
authors added to this application		ß		Co-author:	Role Status		
-authors added to this application	Contact E-Hail	ß	Role †	Co-author:	Role Status Affiliated		

Figure 11 - Add Co-author



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

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

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

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

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

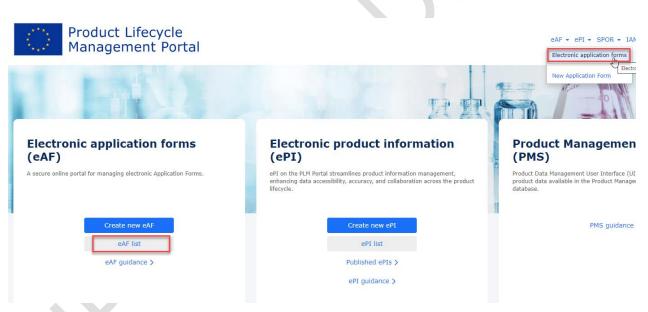


Figure 12 - Application Forms

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

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



• *eAF* Competent Authority User role - all the Application Form(s) of the country for which you have the Coordinator role.

A Pro Ma	nagement Portal								
Home > Application For Deactivated		r Refresh 🧭 Download 🖥					puusaari euro	٩	+ Create New Applicatio
plication m Id	↑Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓Modified On (Access Date)	Status	
R/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	0
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 Fo						ectronic application forms	Electronic product information + S		
Pr Ma	anagement <sup>®</sup> Portal	< Rafresh & Deurisad€				ectronic application forms	Electronic product information + 5	POR + IAM Fo	
Home > Application Fit	anagement <sup>®</sup> Portal	<ul> <li>Aufresh &amp; Dourisat B</li> <li>Application Form Type</li> </ul>	Reference HMI	Created By	Created On	ectronic application forms foodflood by (Liost Garer)			
Home > Application Fit	anagement Portal	Application	Reference HAH European Medicines Agency	Created By Kriatina Puusaari		Modified By	pusseri euro	٩	
Rome > Application Fig Deactivated Directivated Rication m 1d R/24/791	anagement Portal  ms Completed Al Column viability  Triviendly Name	Application Form Type			Created On	Modified By (Last User)	pussari surp Utodfied On (Access Date)	Q Status	
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Processor         Processor           Norme >> Application Processor         Deactivated           Deactivated         R/24/791           plcatoon         R/24/790           gl/24/290         R/24/843           gl/24/843         R/24/843	Anagement Portal	Application Form Type Variation Form Human Variation Form Human Variation Form Human	European Medicines Agency European Medicines Agency European Medicines Agency European Medicines Agency	Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari	Created On 06/05/2024 12:57 07/05/2024 13:50 15/05/2024 12:26 15/05/2024 09:42	Rodilind By (Last User) Kristina Puusaari Kristina Puusaari Kristina Puusaari Kristina Puusaari	Prosessi euro (Access Osto) 15/05/2024 12:37 15/05/2024 12:37 15/05/2024 12:26 15/05/2024 12:26	Q Status Draft Draft Draft Draft	Create New Agel     Create New Agel
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Home > Application For	Terret Portal  Terret Construction  Terret Construct  Terret Construction  Terret Construction  Terret Constructi	Application Firm Types Variation Form Human Variation Form Human	European Medicines Agency European Medicines Agency	Kristiine Puusseni Kristiine Puusseni Kristiine Puusseni Kristiine Puusseni Kristiine Puusseni Kristiine Puusseni Kristiine Puusseni Kristiine Puusseni	Ceated On 06/05/2024 12:57 07/05/2024 12:57 07/05/2024 12:15 15/05/2024 09:12 15/05/2024 09:12 14/05/2024 09:15 06/05/2024 09:15 19/04/2024 16:16	Rodina By (Last User) Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri	Puesseri euro	Status Draft Draft Draft Draft Draft Draft Draft Draft Draft	+ Cruste New Apple

Figure 13 - List of Application Forms

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

In all four tabs, you may use:

- the Search 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. In order to see all previously created forms that you have access to, please click the Load more button.



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

Click the down arrow button  $\heartsuit$ , 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	<ul> <li>Edit Application Form</li> <li>View/Manage Co-authors</li> </ul>	<ul> <li>Edit Applicati</li> <li>Exports</li> <li>Deactivate A</li> <li>Copy Applica</li> <li>View/Manage</li> </ul>	pplication Form tion Form*	
Deactivated	<ul> <li>View Application Form</li> <li>View Co-authors</li> </ul>	<ul> <li>View Applica</li> <li>View Co-auth</li> <li>Exports</li> <li>Copy Applica</li> <li>Reopen Applica</li> <li>Delete Applica</li> </ul>	nors tion Form* ication Form	
Completed	<ul> <li>View Application Form</li> <li>View Co-authors</li> </ul>	<ul> <li>View Applica</li> <li>View Co-auth</li> <li>Exports</li> <li>Reopen Applica</li> <li>Copy Applica</li> <li>Deactivate A</li> </ul>	nors ication Form	
All	Operations depend on the Status Refer to the above operations an		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 Al	l Column visibility  ~	Refresh 🧭 Download 🛙	I.		Search		Q + Create New Application Form
Application orm Id Triendly Name	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
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.

t Deactivated	Completed All	Column visibilit	y 🗸 Refresh 💋 Downlo	ad 🖪		puusaari	¢	Q + Create New Application
application form Id	↑ <sub>Friendly Name</sub>	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:

- 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.

-authors added to this application				and the second second
				Add Co-author
Full Name	Contact Email	Role 🕆	Role Status	
Noel Diamant	noel.diamant@ages.at	EMA Admin Assistant	Affiliated	•
ordinator(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.

Co-authors added to this application				Add Co-author
Full Name	Contact Email	Role 1	Role Status	
Noel Diamant	noel.diamant@ages.at	EMA Admin Assistant	Affiliated	0
oordinator(s) with implicit access to this a	pplication			
full Name	↑ Contact E-Mail	Role	Role Status	
Sindhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated	
Ywydous Nest Ocore O				
selected scope i				
selected scope i		Mome Inducto Management Service +	<ul> <li>An example of the propagation of the second sec second second sec</li></ul>	- LAM Neel Diamant -
selected scope i		Nome Troducts Management Service +	Variation Ferm Human / Version: 1.110 / App	9941 - F. 109994 - H. COULTRAD 22107054
Selected scope i Product Lifecy Management I Type(s) of Change(s) Product Selection	cle Portal	Mome Froducto Management Service -	Variation Form Human / Version: 1.110 / App	Reation for variation to a marketing a RR/23/972 L. Last Saved : 06/31/
selected scope i Product Lifecy Management I Type(s) of Change(s) Product Selection	cle Portal cluded for this application () ash <i>a</i>		Variation Form Human / Version: 1.110 / App Domo test NO / V Search	lication for variation to a marketing at
selected scope i Product Lifecy Management I Type(s) of Change(s) Product Selection Funding	cle Portal	Norre Troducta Hanagement Service -	Variation Form Human / Version: 1.110 / App Demo test ND / V Search Description	lication for variation to a marketing a NV/23/972 (L. Lant Saved : 04/11/1 Ndd Sd
selected scope i Product Lifecy Management I Product Type(s) of Change(s) Product Selection Product Selection Rafe	cle Portal cluded for this application () ash <i>a</i>	Selected	Variation Form Human / Version: 1.110 / App Domo test NO / V Search	Nation for variation to a marketing as NV23/972 (Litant Saved : 06/13/7 Note So Note Soft and Soft
selected scope i Product Lifecy Management I Proding Type(s) of Change(s) Product Selection Product Type(s) of Change(s)	clue Portal clusted for this application () set @ 1 Scope A.5.b the settivities for which the manufacturer/importer is responsible	Selected	Variation Ferm Human / Version: 1.110 / App Domo text ND / Vi Search Description A.S ADMINISTRATIVE CHANGES - Change in the name an ripmpeter of the fielded product (field-ding bath: release or the advites field which the manufacturary/imports is response	Nation for variation to a marketing as NV23/972 (Litant Saved : 06/13/7 Note So Note Soft and Soft

Showing 1 to 1 of 1 entries
Save Validate Cancel Export



#### Procedural information will also all be cloned

	Product Lifecycle Management Portal		A Home	Products Management Service +	ePI =	Application Forms +	Forum SPOR +	LAM Nosl Diamant +	
e	Pending 😨 Procedural Info	prmation						n for variation to a marketing authorisatio 1972 🛓 Last Saved : 06/11/2023 14:2	
<i>8</i> 6	Product Selection Pending	Please add at least one Contact Person.							
ж,	Type(s) of Change(s) Pending	Procedural Information						>	
	Procedural Information	Name and Address of MA Holder (Applicant) $\mathbb O$						>	
ં	Proposed Changes	Contact Person ©						>	
Ś	Finalisation	Save Validate Cancel Export							

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

Pending X Procedural Informa	ition			Variation Ferm Human / Version: 1.110 / Applicatio	n for variation to a marketing au /972 🛃 Last Saved : 06/11/
Product Selection	Please add at least one Con	tact Person.			
Type(s) of Change(s) Pending	Procedural Igfor	mation			^
Procedural Information Pending	Domain * Type of Application	Human use Single Regulatory Activity	Type of Authoritation	Variation Procedure Number * Procedure Number †	
Proposed Changes Peoding	Including a line extension Worksharing ①		Decentralised Procedure National Procedure	977/01234/123	0
Finalisation Pending	16 / Supergrouping		Change(s) concern(s) (for Type II and Type II variations only, Bck all changes applicable)	Reference Hember Portugal State •	~
	Name † Variation Type IB		D Name		



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

Product Manage	Lifecycle Advances Management Service - eR - Application Forms - Forum SROR - LAM Noel Ok ment Portal	amant -
Pending X Proposed Changes	Variation Firm Human / Veinton: 1.110 / Application for variation to a mai Discons test ND - / VAR/23/972 🕹 Last Saved :	
Product Selection	Precise Scope and Background for Change D	^
Type(s) of Change(s) Pending	Precise Scope for Change * Precise Scope for Change	
Procedural Information Pending		
Proposed Changes Pending		
Finalisation Pending	Background for change and justification for grouping, worksharing and classification * Background for change and justification for grouping, worksharing and classification	
	d' segenti - s - B / U ⊉ ≧ = = = = = m = m = = = 0 = 3, x' = ≡ pf 14 2 ⊂ 5, ≣ - 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 acts needs to be updated.	osed
	Product MA Number(s) + Scope(s) Recommended Change(s) Proposed Change(s)	
	D There are no records to display.	
	Other Applications (0)	>
	Save Vulidate Cancel Export	

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

## 2.1.5. Delete form function

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



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

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

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

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

## 2.2. Product Selection

- 2.2.1. How to access previously created/edited electronic Application Form(s)
- 2.2.2.Industry users with an active EMA account and with the eAF Applicant Manager role can edit existing Application Forms which have been created by them;

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

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

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



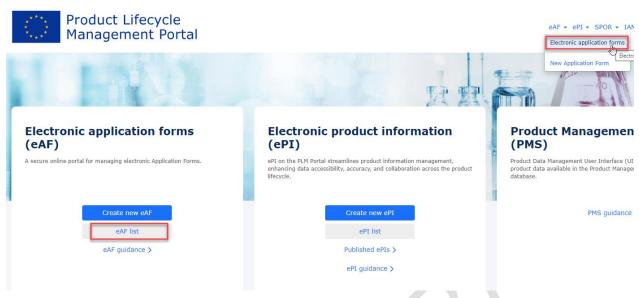


Figure 12 - Application Forms

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

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

Ma	5								
Home > Application For Deactivated		Refresh 🔉 Download 🖥					puusaati euro	۹	+ Create New Applicati
lication m Id	TFriendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓ <sup>Modified On</sup> (Access Date)	Status	
R/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	
		<ul> <li>× Fafrah Z Conniad ₿</li> </ul>				ectronic application forms	Electronic product information + Si	NOR - IAM Foru	Ecod m Kristiina Puusaa † Create New Agga
Home > Application Fit	anagement Portal	Application	Reference MAI	Orestel By	Created On	Modified By	puusseri suro		
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Home > Application Fin Deactivated plication plication plication plication plication	anagement <sup>®</sup> Portal	Application Form Type			Created On	Hodified By (Last User)	puttaari kure J.Modified On (Access Date)	Q	
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Press         Press           Home > Application Pro         Deactivated           Deactivated         R/24/791           R/24/791         R/24/793           R/24/843         R/24/843           R/24/843         R/24/843	Anagement Portal	Application Form Type 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	Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari	Created On 06/05/2024 12:57 07/05/2024 13:50 15/05/2024 12:26 15/05/2024 09:42	Rodfied By (Lest User) Kristine Puusaari Kristine Puusaari Kristine Puusaari Kristine Puusaari	20058871 60/0      20058871 60/0      20052024 12:39      15/05/2024 12:37      15/05/2024 12:26      15/05/2024 01:42      15/05/2024 00:42	Q Status Draft Draft Draft Draft Draft Draft	Cinate New Appl     C
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Processor         Processor           Inner > Application in         Decessor           Inner > Application in         Inner > Application in           MIC24/791         HIC24/791           MIC24/793         HIC24/793           MIC24/794         HIC24/794	Anagement Portal	Application Firm 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	Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari	Created On 06/05/2024 12:57 07/05/2024 13:50 15/05/2024 13:26 15/05/2024 09:42 14/05/2024 09:15	Rodified by (Seat Garr) Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri Kristine Proseeri	Eustrant euro     Constant euro     Consta	Q Status Draft Draft Draft Draft Draft Craft	Consta New Appl     Consta New Appl     Consta New Appl     Constant New Appl     C
Image         Application in           Deactivation         Construction           R1/24/795         R1/24/795           R1/24/796         R1/24/796           R1/24/796         R1/24/796           R1/24/796         R1/24/796           R1/24/796         R1/24/796	Anagement Portal	Application Form 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	Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari	Created On 06/05/2024 12:57 07/05/2024 13:50 15/05/2024 13:50 15/05/2024 13:26 15/05/2024 09:42 14/05/2024 09:14 06/05/2024 09:15	Rodified by (Seat Garry) Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer	Euusaari euro     Chodiniad On     (Access Usia)     15/05/2024 12:39     15/05/2024 12:37     15/05/2024 12:26     15/05/2024 12:26     15/05/2024 01:42     15/05/2024 01:1     0/05/2024 01:1     0/05/2024 11:49     06/05/2024 11:41     26/04/2024 00:22	Q Blatus Draft Draft Draft Draft Draft Draft Draft Draft Draft	Create New Appl     Create New Appl     Eff Application Rem     Wou/Nanage Co-acthol     Application Rem     Mou/Nanage Co-acthol     Application Rem
Image: Normal Science         Application Procession           Image: Normal Science         Image: Normal Science           Image: Normal Science         Image: Normal Science <t< td=""><td>anagement Portal</td><td>Application Firm Type Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human Variation Form Human</td><td>European Medicines Agency European Medicines Agency</td><td>Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari</td><td>Created On O6/05/2024 12:57 07/05/2024 13:50 15/05/2024 13:50 15/05/2024 03:12 14/05/2024 09:13 06/05/2024 09:13 06/05/2024 09:13 15/04/2024 09:53 19/04/2024 16:16</td><td>Rodified by (Cast Garry) Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer</td><td>Evuxeari euro</td><td>Craft Draft Draft Draft Draft Draft Draft Draft Draft Draft Draft Draft Draft</td><td>Create New Appl     Create New Appl     C</td></t<>	anagement Portal	Application Firm 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	Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari Kristiina Puusaari	Created On O6/05/2024 12:57 07/05/2024 13:50 15/05/2024 13:50 15/05/2024 03:12 14/05/2024 09:13 06/05/2024 09:13 06/05/2024 09:13 15/04/2024 09:53 19/04/2024 16:16	Rodified by (Cast Garry) Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer Kristine Proseer	Evuxeari euro	Craft Draft Draft Draft Draft Draft Draft Draft Draft Draft Draft Draft Draft	Create New Appl     C

Figure 13 - List of Application Forms

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

In all four tabs, you may use:

- the Search  $\mathbf{Q}$  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. In order to see all previously created forms that you have access to, please click the Load more button.

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



Click the down arrow button  $\heartsuit$ , 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	<ul> <li>Edit Application Form</li> <li>View/Manage Co-authors</li> </ul>	<ul> <li>Edit Applicati</li> <li>Exports</li> <li>Deactivate A</li> <li>Copy Application</li> <li>View/Manage</li> </ul>	pplication Form ition Form*	
Deactivated	<ul> <li>View Application Form</li> <li>View Co-authors</li> </ul>	<ul> <li>View Applica</li> <li>View Co-auth</li> <li>Exports</li> <li>Copy Applica</li> <li>Reopen Applica</li> <li>Delete Applica</li> </ul>	nors ition Form* ication Form	
Completed	- View Application Form - View Co-authors	<ul> <li>View Applica</li> <li>View Co-auth</li> <li>Exports</li> <li>Reopen Applica</li> <li>Copy Applica</li> <li>Deactivate A</li> </ul>	nors ication Form	
All	Operations depend on the Status Refer to the above operations an		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).

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

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

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



Home > Application Forms					Search		
raft Deactivated Completed All	Column visibility 👻	Refresh 🧷 Download	5		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.

## 2.2.4. 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.

t Deactivated	Completed All	Column visibilit	y 🗸 Refresh 💋 Downlo	ad 🖪		puusaari	¢	Q + Create New Application
application form Id	↑ <sub>Friendly Name</sub>	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				10,000
				Add Co-author
Full Name	Contact Email	Role ↑	Role Status	
Noel Diamant	noel.diamant@ages.at	EMA Admin Assistant	Affiliated	٢
ordinator(s) with implicit access to this	application			
ull Name	↑ Contact E-Mail	Role	Role Status	
ndhu 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.

o-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 this applic				
oordinator(s) with implicit access to this applic	ation			
Full Name	↑ Contact E-Mail	Role	Role Status	
Sindhu Bandari	sindhu.bandari@ext.ema.europa.eu	Applicant Coordinator	Affiliated	
8	cloned			
в	9	Home Products Hanagement Service +	ePI +   Application Forms +   Forum   SPOR +	LNN   Noel Diamant +
selected scope is	9	Home Products Hanagement Service -	Variation Form Human / Vension: 1.110 / Applicati	1 1000 P 11 F 00 11 10 00 22 P 00 P
selected scope is Product Lifecycle Management Por Product Product Product Variations included	9	Home Products Hanagement Service +	Variation Form Human / Vension: 1.110 / Applicati	on for variation to a marketing au
selected scope is Product Lifecycle Management Por Type(s) of Change(s)	ertal d for this application?	A Home Produtta Hanagement Service +	Variation Form Human / Vension: 1.110 / Applicati	on for variation to a marketing au
Selected scope is Product Lifecycle Management Por Type(s) of Change(s) Product Selection Fording	ertal d for this application?	A Home Products Management Service -	Variation Form Human / Vention: 1.110 / Applicati Demo test NP / VAR/2	on for variation to a marketing au 3/972 g, Last Saved : 06/11/2
selected scope is Product Lifecycle Management Por Type(s) of Change(s) Product Render Type(s) of Type(s) of Type(s) of Type(s) of Type(s) of Type(s) of Type(s) of	ertal d for this application? scope b the activities for which the manufacturer/importer is responsible do no	Selected	Variablen Form Human / Vension: 1.110 / Applicab	on for sanation to a marketing au 1972 d. Last Saved : 04/11/2 Add Se settless of a manufactures ty control testing alles) -
Selected scope is Product Lifecycle Management Por Type(s) of Change(s) Product Selection Product Selection Product Selection Type(s) of Change(s)	ertal d for this application? scope b the activities for which the manufacturer/importer is responsible do no	Selected t include batch 1	Variation Form Human / Venion: 1.110 / Applicati Demo test No / VAN/2 Search Description A-5.0 - ADVIDISTRATIVE CIMAVES - Change in the name and/or r/importer of the finished product (including batth release ar and/or r/importer of the finished product (including batth release ar and/or r/importer of the finished product (including batth release ar and/or r/importer of the finished product (including batth release ar and/or r/importer of the finished product (including batth release ar and/or r/importer of the finished product (including batth release ar and/or r/importer of the finished product (including batth release ar and/or released batth released batth r	on for sanation to a marketing au 1972 d. Last Saved : 04/11/2 Add Se settless of a manufactures ty control testing alles) -

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#### Procedural information will also all be cloned

	Product Lifecycle Management Portal		A Home	Products Management Service +	ePI =	Application Forms +	Forum SPOR +	LAM Nosl Diamant +	
e	Pending 😨 Procedural Info	prmation						n for variation to a marketing authorisatio 1972 🛓 Last Saved : 06/11/2023 14:2	
<i>8</i> 6	Product Selection Pending	Please add at least one Contact Person.							
ж,	Type(s) of Change(s) Pending	Procedural Information						>	
	Procedural Information	Name and Address of MA Holder (Applicant) $\mathbb O$						>	
ં	Proposed Changes	Contact Person ©						>	
Ś	Finalisation	Save Validate Cancel Export							

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

Pending X Procedural Informa	tion			Variation Form Human / Version: 1.110 / Application	
Product Selection	Please add at least one Con	tact Person.			
Type(s) of Change(s) Pending	Procedural Igfor	mation			^
Procedural Information Pending	Domain * Type of Application	Human ute Single Regulatory Activity	Type of Authoritation	Variation Procedure (tumber * Procedure Number †	
Proposed Changes Peoding	Including a line extension Worksharing ①		Decentralised Procedure National Procedure	PT/W1234/123	0
Finalisation	16 / Supergrouping		Change(q) concern(q) (for Type II and Type II variations only, lick all changes applicable)	Reference Hember State * Portugal	*
	Name † Variation Type IB		D Name		



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

Product I Managen	.ifecycle	iamant -
Pending 😨 Proposed Changes	Variation Form Human / Vanion: 3.110 / Application for variation to a ma Domo test ND - / VAR/23/9/2 🕹 Last Saved :	
Product Selection Pending	Precise Scope and Background for Change ①	>
Type(s) of Change(s) Pending Z	Precise Scope for Change * Precise Scope for Change	
Procedural Information Pending		
Proposed Changes Pending	⊄ Fant • Box • B / U ℓ• ≙• ≡ ≡ = = = = = = = = = = = = = = = = =	
Finalisation Pending	Background for change and justification for grouping, worksharing and dassification * Background for change and justification for grouping, worksharing and dassification	
	¢f Segne U •   € •   Β J U ⊉ [A] = = − − − = ⊞ ≡ ≡ ∞ ∞ ×, × − ≡ № № 2 ⊂ ⊗ ≡• Ω	
	Present and Proposed Changes	^
	Please add a Present and Proposed change for sight 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 shuttared product data needs to be updated.	posed
	Product HA Number(s) + Scope(s) Recommended Change(s) Proposed Change(s)	
	There are no records to display.	
	Other Applications®	>
	ave Vulidate Cancel Export	

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

## 2.2.5. Delete form function

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



## 2.2.6. How to add a product in an Application Form

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

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

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

- 1. Access an existing or create a new Application Form. See sections 1.1.1, 2.1.2 and 2.1.3 for further details
- 2. In the Product Selection page, as a first step in a new application form click on + Add Product button.

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

Product Selection Pending	_		erned by this applica y v Show 10 rows				As	sociate MRP N	r. Sea	rch		Q + Add Produ
Type(s) Change( Pending	of 5) ∑	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
Procedu Informa Pending	ion	owing 0 to 0 of	f 0 entries		N	lo data availabi	le in table					

Figure 14 - Add Product

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

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

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

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Column	risibility 🗸 Refres	n <i>Ø</i> View Selecte	d Products							Search My Products
	↑ Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
	Abasaglar 100 Units/ml - Solution for injection	Solution for injection	Insulin glargine	European Union	Eli Lilly Nederland B.V.	EU/1/14/944	EMEA/H/C/002835			
•	Abecma 260- 500 x 10° cells - Dispersion for infus	Dispersion for infusion	Idecabtagene vicleucel	European Union	Bristol-Myers Squibb Pharma EEIG	EU/1/21/1539	EMEA/H/C/004662			
0	Abevmy 25 mg/ml - Concentrate for solution for in	Concentrate for solution for infusion	Bevacizumab	European Union	Mylan IRE Healthcare Limited	EU/1/20/1515	EMEA/H/C/005327			
•	Abilify 1 mg/ml - Oral solution	Oral solution	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471			
	Abilify 10 mg - Orodispersible tablet	Orodispersible tablet	Aripiprazole	European Union	Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276	EMEA/H/C/000471			
					Otsuka					

Figure 15 - List of Products

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

	<sup>†</sup> Full Name	Authorised Dose Form	Active substance(s)	Authorisatio Country	on MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
2										
2										

#### Figure 16 - View Available Products

If you do not find the product you are intending to select, click on the Refresh button. Otherwise, please double check your roles. The product could also be associated with another MAH. You can check the full product list in the 'SPOR' menu by selecting the Medicinal Products option (you will need to be signed in to see the list content). This will open a full list of authorised products.



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

#### Click on the Save button

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

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

VISIDIIICY	<ul> <li>Show 10 rows Refresh 2</li> </ul>				Associate MRP Nr. Search	Q + Add P
			Q			Nr. of
	Full T <sup>Name</sup>		Authorised Active Dose Form Substance	Authorisation MA Country Holder	MA Nr. MRP / CP Nr.	PMS ID Selected Packages
	ABILIFY 1 mg/ml oral solution		Oral solution Aripiprazole E	European Union Otsuka Pharmaceutical Netherlands B.V.	EU/1/04/276 EMEA/H/C/000471	0/3
Sel	ected Packaged Medicinal Product(s)					Search
	Full Nome	Pack Size	Package Description	MA Number	↑ <sup>Package ID</sup>	Authorisation Status
		1 bottle + 1 cup + 1 calibrated dropper	Packaging: bottle (PET), Package size: 1 bottle			Valid - Transferred marketing authorisation
8	ABILIFY 1 mg/ml oral solution	1 bottle + 1 cup + 1 calibrated dropper	+ 1 cup + 1 calibrated dropper, Content: 50 ml			
8	ABILIFY 1 mg/ml oral solution	1 bottle + 1 cup + 1 calibrated dropper	+ 1 cup + 1 calibrated dropper, Content: 50 ml Packaging: bottle (PET), Package size: 1 bottle + 1 cup + 1 calibrated dropper, Content: 150 ml			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 the medicinal product that you do not need, please click the 'Add product' button again and deselect (untick) the selected products not needed in this application and save the updated selection. The proceed as previously.

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



$\sim$	Completed Completed Completed												tion to a marketing authorisu
Ø	Product Selection Completed		concerned by this a plumn visibility v S		Refresh 💋					Associate MRP Nr.	Search	٩	+ Add Product
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	~	Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG- 200036101) LOC	1- 19575UAT		UAT600010687758	600010687758		0/0
<b>i</b>	Proposed Changes Pending X		o 1 of 1 entries Validate Cancel	Export									
				F	igure 1	8 - Save	and Valida	ate Butt	ons				

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

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

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

Ô	Completed Selection												tion to a marketing authorisi ved : 09/09/2022 13:12:0
0	Product Selection		oncerned by this a umn visibility 🗸 S		tefresh <i>2</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	~	Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG- 200036101) LOC	1- 19575UAT		UAT600010687758	600010687758		0/0
$\mathbf{O}$	Proposed Changes Pending	Showing 1 to Save V	1 of 1 entries alidate Cancel	Export									

Figure 19 - Associate MRP Nr. Button

#### 2.2.8. How to delete a product from an Application Form

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

- 1. Access an existing or create a new Application Form. See sections 1.1.1, 2.1.2and 2.1.3 for further details
- 2. In the Product Selection page, click on + Add Product



Product Selection	Products concerned by this application											
Pending 🛛 🛣	Colu	ımn visibility	Show 10 rows	Refresh 💋			As	sociate MRP N	r. Sea	irch		Q + Add Product
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
					N	o data availab	le in tabl	9				
Procedural Information Pending	Showii	ng 0 to 0 of	0 entries									

Figure 20 - Add Product

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

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

**4.** Click on <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.

$( \vee )$	Pending 📓 Variation Form Human / Application for nariation to a marketing autho Product Selection> View / Select Product 🗁 Users / VAR222/586 🛓 Last Saved : 09/09/2022 21:41											
$\mathcal{O}_{\Theta}$		Column	visibility 🗸 Refi	resh 💋 View Availat	ole Products						S	earch My Products Q
X		□ ↑ F	ull Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
			Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG-200036101) LOC	1- 19575UAT		UAT600010687758	600010687758	PRD/0000541100
		☑ 0 z	Advantan Milch ),1% Emulsion sur Anwendung auf der Haut	Cutaneous emulsion		Republic of Austria	UAT ORG (ORG-200036101) LOC	1- 22211UAT	AT/H/0102/001UAT	UAT600010575194	600010575194	PRD/0000541057
$\mathbf{\vec{o}}$	Showin Save	g 1 to 2 of Cano	_									



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

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

The packaged medicinal products, linked to the variation scopes in Present and Proposed section are those that will be displayed in the section 2 of the pdf export. The presentations that have not been

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

# 2.3. Type(s) of change(s)

### 2.3.1. How to add a variation scope in an Application

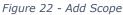
Industry users with the eAF Applicant Manager role or the eAF Applicant Coordinator role and NCA users with the eAF Competent Authority User role may add/delete scopes in an Application Form.

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

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

- 1. Access an existing or create a new Application Form. See sections 1.1.1, 2.1.2and 2.1.3 for further details
- 2. In the Type(s) of Change(s) page, click on Add Scope

Pending Type(s	∑ s) of Change	(5)						
		Variations included for this application ${}^{}$ Refresh $\not$				Samh Add Scope		
	e(s)of nge(s) ≆ ∑	↑ Scope	Selected	No data available in table	Description			
	edural rmation	Save Validate Cancel Export						



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

以	<sup>Pendag</sup> ∑ Type(s) of Change(s)> Add/Edit Scope	
0	Selected Scope	
<i>х</i> ;		
ď	I	
	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.

	cope	the asterisk (*) v character
		c.i
Choose one record	d and click Select to continue	-
×	Name 1	
	C.I.1.a The medicinal product is covered by the defined scope of the procedure	
	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 s	ubmitted by the MAH
	C.I.1.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 MA	н
	C.I.10 Change in the frequency and/or date of submission of periodic safety update reports (PSUR) for human medicinal products	
	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 i	s required*
	C.I.11.z Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II	
	C 1.11 z Other oblinations and conditions (e. n. anneed wordina + ORD template)	
< 1 2	3 4 5 >	

Figure 24 - Example of Search using Classification Code

Select Scope		×
		*atc Q
Choose one record and click	: Select to continue	
~	Name ↑	
	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 h 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)*	control 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 biologic kes place	al / immunological / immunochemical method ta
< 1 2 3 >		
		Select Cancel Remove value

Figure 25 - Example of Search using Wild Card and Text

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

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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.

$\mathcal{O}_{\Theta}$	Selected Scope		
	C.I.6.a Addition of a new therapeutic indication or modification of an approved one	×	۹
	Figure 26 - Cancel and Select Scope		

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

Selected Scope			_
C.I.6.a Addition of a n	ew therapeutic indication or modification of an approved one	×Q	
Select Procedure Type			
and a second sec			
		٩	Launch lookup modal

Figure 27 - Select Procedure Type

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

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



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

Figure 28 - Select Procedure Type

9. Depending on the selected Procedure type, further options will become available for 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	DD/MM/YYYY
Identifier *	
B.I.b.2.a - Variation Type IA - 1	
Implementation Date Note	
Select Conditions	
□ Conditions ↑	Note ①
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.	
Select Documentations	
□ Cocumentations ↑	Note ①
Amendment of the relevant section(s) of the dossier (presented in the EU-CID 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 id specifications for impurities (if applicable).	
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	

Figure 29 - Option Selection

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

Selected Selected Decription     Procedure Selected Selected     B.b.b.2.a. GUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Minor changes to an approved test procedure 1     B.b.b.2.a. GUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Minor changes to an approved test procedure 1     Procedure Type Internet                 Procedure Type Internet                       Procedure Type Internet   Procedure Type    Procedure Type   Procedure Type   Procedure Type    Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure Type   Procedure	0	Product Selection	Variations inclue Refresh	ded for this application ອ	D					Search	Add Scope
Information Pending T Proposed Changes Pending T Proposed Pending T Proposed Changes Pending T Proposed Changes Pending T Proposed Changes Pending T Pending T Proposed Changes Pending T Pending T Pen	以				s to an approved test procedure	Selected		B.I.b.2.a - QUALITY Change in test proce material/reagent/int	dure for active substance or starting ermediate used in the manufacturing	process of the active	•
Changes J entries		Information	~				Impleme	ntation Date	Implementation Date Note		
Save Validate Cancel Export	$\mathbf{\vec{o}}$	Changes		-							

Figure 30 - Summary of Selection

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

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

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Variations in	cluded for this application $^{}$					
Refr	esh 🖉				Search	Add Scope
	<sup>†</sup> Scope		Selected	Description		
Þ	C.I.6.a Addition of a new therapeutic indication or m	odification of an approved one		C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANCE NARY MEDICINAL PRODUCTS - Change(s) to therap new therapeutic indication or modification of an app	eutic indication(s) - Addition of	
	<sup>↑</sup> Identifier	Procedure Type	Implementation Da	te Implementation Date Note	Article 5	
$\sim$	C.I.6.a - Variation Type II <mark>- 1</mark>	Variation Type II				•
$\sim$	C.I.6.a - Variation Type II - 2	Variation Type II				•
2 entries						
Showing 1 to :	1 of 1 entries					
Save Va	lidate Cancel Export					

Figure 31 - Add Scope

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

### 2.3.2. Clone scope

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

Refresh 🖉				Search		Add Scope
↑ <sub>Scope</sub>	Selec	ted	Description			
A B.1.b.2.a Minor changes to an approved test procedure	3		B.I.b.2.a - QUALITY CHANGES - ACTIVE 5 active substance or starting material/reag ance - Minor changes to an approved test	ent/intermediate used in the manufacturin-		
	↑ Identifier	Procedure Type	Implementation Date	Implementation Date Note	Article 5	
<u>^</u>	8.1.b.2.a - Variation Type IB	Variation Type IB				•
↑ Selected	Condition		Note			
0	Appropriate validation studies have been show that the updated test procedure is					
	The method of analysis should remain th but not a different type of column or me		n length or temperature,			
8	The test method is not a biological/immu biological reagent for a biological active robiological methods).					
	There have been no changes of the total d.	impurity limits; no new unquali	fied impurities are detecte			
l 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	appropriate), including a descri	iption of the analytical me			
11	Comparative validation results or if justil test and the proposed one are equivalen of a new test procedure.					
						12

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



fresh Ø				Search		Add Scop
↑ <sub>Scope</sub>	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	<ul> <li>Change in test procedure s of the active substance -</li> </ul>	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

Variations included for this appl	ication ()					
Refresh 💋				Search		Add Scope
↑ <sub>Scope</sub>		Selected	Description			
A B.I.b.2.a Minor char	nges to an approved test procedure	3	test procedure for active substan	ACTIVE SUBSTANCE - Control of ac ce or starting material/reagent/inte ubstance - Minor changes to an ap	rmediate used in the	man 🕑
	↑ 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				٥
						dit Scope Im
entries						Delete
Showing 1 to 1 of 1 entries						
Save Validate Cancel	Export					

• 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 1.1.1, 2.1.2and 2.1.3 for further details



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

<i>8</i> 6	Product Selection	Variations included for this application $^{}$ . Refresh $~~\boldsymbol{\mathcal{G}}$		Seech	Add Scope
以	Type(s) of Change(s) Pending	Scope S.Lb.2.a Minor changes to an approved test procedure	Selected	Description B.Lb.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/insagent/instremediate used in the manufacturing process of the active substance - None changes to an approved test procedure	Delete
	Procedural Information Pending X	Save Validate Cancel Export		_	

Figure 32 - Delete Scope

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

ariations incl	luded for this application (						
Refre	sh 🔁					Search	Add Scope
	<sup>↑</sup> Scope		Selected	Description			
$\sim$	C.I.6.a Addition of a new therapeutic indicatio	n or modification of an approved one	2	NARY MEDICIN	Y, EFFICACY, PHARMACOVIGILANCE AL PRODUCTS - Change(s) to therap c indication or modification of an app	eutic indication(s)	
	1 Identifier	Procedure Type	Implementation	Date	Implementation Date Note	Article 5	
$\sim$	C.I.6.a - Variation Type II	- 1 Variation Type II					•
$\sim$	C.I.6.a - Variation Type II	- 2 Variation Type II					Edit Scope

Figure 33 - Edit Scope

#### 2.3.4. How to delete a scope in an application

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

- **3.** Access an existing or create a new Application Form. See sections 1.1.1, 2.1.2and 2.1.3 for further details
- **4.** In the Type(s) of Change(s) page, click the small arrow at the end of the scope you wish to delete and select 'Delete'.

<i>8</i> 6	Product Selection	Variations included for this application $^{}$ . Refresh $~\mathcal{G}$		Search Add So	cope
	Type(s) of	↑ Scope	Selected	Description	
X,	Type(s) of Change(s)       Pending	<ul> <li>B.I.b.2.a Minor changes to an approved test procedure</li> </ul>	1	B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/regent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure	
	Procedural Information Pending	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.



Refresh	d for this application $^{(i)}$				Search	Add Scope
	<sup>†</sup> Scope		Selected	Description		
^	C.I.6.a Addition of a new therapeutic in	dication or modification of an approved one	2	C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILAN NARY MEDICINAL PRODUCTS - Change(s) to the new therapeutic indication or modification of an i	rapeutic indication(s) - Addition of	
	1 Identifier	Procedure Type	Implementation D	ate Implementation Date Note	Article 5	
$\sim$	C.I.6.a - Variation 1	Type II - 1 Variation Type II				٢
$\sim$	C.I.6.a - Variation 1	ype II - 2 Variation Type II			Edit So Delete	ope

Figure 35 - Edit Scope

## 2.4. Procedural Information

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

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

Figure 36 - Procedural Information Section Overview

# 2.4.1.Procedural Information

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

It is not possible to manually edit these selections.

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

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

Figure 37 - Sub-section: Procedural Information

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

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

- Medical Device; this tick box is available for all procedure types and should be selected if the section 4d of the pdf needs to be filled i.e. for classifications (scopes) related to Medical Devices e.g. B.IV.1.a.1.
- Change(s) concern(s); this sub selection is only visible if Type IB or Type II has been selected in Type(s) of Change(s) section.
- Variation Procedure Number; An editable free text field to include the variation procedure number for validation-response, or for example the WS or IG number. For CAPs this is an optional field.



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

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.

Name and Address of MA Holder (Applicant)		^
Reference MAH ① European Medicines Agency Org ID ORG-100013412 Address Domenico Scarlattilaan 6 Amsterdam 103 HS Netherlands	LOC ID LOC-100020264 Customer Account Number  Modified On	
Phone Number Provide a telephone number	12/09/2022 19:09 Email	]

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



### 2.4.3.Contact Person

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

<b>NOTE:</b> there is a known issue which displays also some non-active locations for the organisations	in
the Contact person section.	

**1.** Click the + Add button

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

Figure 40 - Contact Person

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

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

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

Figure 41 - Create Application Contact

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



Looku	p records	<ul> <li>Francé a le concret i</li> </ul>	en e	×
				*iaitos Q
Choose or	ne 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

Figure 42 - Lookup Records

- 4. Click on the Select button and you will be taken back to the Create Application Contact page
- 5. Click on the Save button and you will be taken back to the Procedural Information main page
- **6.** Click on the <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.

$\mathbf{\vec{o}}$	Pending 🚡 Proposed Changes		
8	Product Selection	Precise Scope and Background for Change	>
ぷ	Type(s) of Change(s)	Present and Proposed Changes	>
	Procedural Information Pending	Other Applications	>
Ì	Proposed Changes Pending		
		Figure 12 Drepeed Changes	

#### Figure 43 - Proposed Changes

#### 2.5.1. Precise Scope and Background for Change

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

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



- **1.** Access an existing or create a new Application Form. See sections 1.1.1, 2.1.2and 2.1.3 for further details
- 2. Enter the Precise Scope for Change and Background for change in the corresponding free text fields. You can paste text into this field from another document (plain text only will be copied, you will need to manually edit the text if you wish to add for example <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		~
Precise Scope and background for change	Background for Change		
Frecise Scope for Linange	Specify the precise present and proposed working or specification, including dustiler action number(s) at the lowest possible level. Click here to read the guidance: Guidance for applicants for the preparation of the precise scope section of the variation application form		
of Font • Size • B I U ,	<u> 2</u> • <u>∧</u> • ≡ ≔ •= •	医菌 泡 向 キーオー ω 岡 州 羽 ツ (* δ) ■・Ω	
Background for Change			
Enter text			
	🖉 * 🗛 📰 🖂 🖷 🗰 🕫	E Ξ Ξ Φ Φ, X, X' == M H H Y C b = Ο	

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.



Product Selection Pending	Precise Scope and Background for Change D	>
Type(s) of Change(s) Pending	Present and Proposed Changes	^
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 test / Organisation changes, please check if structured product data needs Proposed Change Pr	s to be updated. resent/Proposed
Proposed Changes Pending	Product MA Number(s) Scope(s) Recommended Change(s) Proposed Change(s)	
Finalisation	Other Analystics	
	Other Applications©	>

## 2.5.2.1. Present and Proposed Text Changes

Ж,	Type(s) of Change(s) Pending ∑		Present and Proposed Changes		^	
Ē	Procedural Information	6	Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based check if structured product data needs to be updated. Proposed Change	on your scope se		
ं	Proposed Changes	1	□ Product MA Number(s) ↑ Scope(s) Recommended Ch	ange(s)	Proposed Change(s)	
$\otimes$	Finalisation		Other Applications ①		>	
			Save Validate Cancel Export		,	

Figure 46 - Present and Proposed Changes

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

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



esent and Propos	ed Value(s)	Selected Scope(s)	Selected Medicin	al Product(s)								
Present *							Proposed *					
Enter text							Enter text					
Font Organisation Det		I U <u>2</u> - 1	4• ≡ ≔ -= -	= n = = =	ન્દ્ર ્		S Font	• Size • B	I U 2- A	• = = •= •		କେତ୍ର ଅ
Organisation N ot Selectable ↑	Organisation N ame (Present O rganisation)	Organisation Lo cation (Present Organisation)	Organisation Id (Present Organi sation)	Full address (Pr esent Organisat ion)		Modified On (Pr esent Organisat ion)	Organisation N ame (Proposed Organisation)	Organisation Lo cation (Propose d Organisation)		Full address (Pr oposed Organis ation)		
No	European Medicin es Agency	LOC-100010800	ORG-100006175	30 Churchill Place London E14 5EU United Kingdom	[ INACTIVE ] Eur opean Medicines Agency	17/07/2022 22:0 7	European Medicin es Agency	LOC-100018793	ORG-100013412	Orlyplein 24 104 3 DP Amsterdam Netherlands	European Medicin es Agency	12/09/2022 19 9
No	Austrian Agency For Health And Fo od Safety		ORG-100003912		Austrian Agency For Health And Fo od Safety	12/09/2022 14:0 9	Austrian Agency For Health And Fo od Safety		ORG-100003912		Austrian Agency For Health And Fo od Safety	

Figure 47 - Present and Proposed Values

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

esent <sup>#</sup>	Proposed *
Change 1 relates to the update of this and that.	Change 1 relates to the update of this and that.
Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and that.	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. Chan relates to the update of this and that.
	Proposed Owenges + Present and Proposed Velac(s) 🗁 # HMM21(sels Georgesine / HM21564 (sels and - HM22)
	Terminal and Temperal Table(s) Terminal Terminal Terminal
	Termin
	System birk
	Operation 1         Specialize 1         Specialize 2         Addition 2         Non-Digate         Specialize 2
	ni Sdochlar, republicka (Begunianisti seles) seles (n. 1997) ka Euguerindus (Ed.2002) Billioni (Ed.2002)
	Unit Column         Column Column         Column Column         Number Science         Number Scien
	🕐 brane o GMI datalee kalona Takana ana dha agaratana adhaa agaratana adhaa dha agaratana adhaa agaratana agaratana adhaa agaratana agaratana adhaa agaratana adhaa agar
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 that	Change 1 relates to the update of this and that. Change 1 heistes to the update of this and that. and that:
න් Segoe UI • 9 • 18 / U ℓ• A• ≡ ≔ +≠ ** ■ = = = ත ල x, 💽 ▼	
	భ Segoe UI • 9 • B I U ⊉• దౖ• ⊟ ≔ •≡ •≡ • ≣ ≣ ≣ ⊒ లె ంు

Figure 48 - Present and Proposed Values - Toolbar Options

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



**the free text in the** Present and Proposed fields before **selecting the organisations that are impacted from OMS**. Changes added to the Present and Proposed fields **will be lost** if you enter these first and then add an organisation details using the <u>+ Add</u> 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.

Present and Proposed Value(s) Selected Scope(s) Selected Medicinal Product(s)	
Present *	Proposed *
Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and that.	Change 1 relates to the update of this and that.     Change 1 relates to the update of this and that.     Change 1 relates to the update of this and that.     Prevent the update of this and that.     Prevent the update of freezed WheelD

Figure 49 - Selection of Scope and Medicinal Product

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

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

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



Present	and Proposed Value(s) Selected Scope(s) Selected Me	sdicinal Product(s)		
Colum	n visibility 🗸			Filter
	Identifier	1 Scope	Recommended Change(s)	Description
o	B.II.b.1.e - Variation Type IB - 1	B.III.b.1.e.Sits 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 - QUALTY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place. except bach-release. bach control, primary 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
	B.II.b.2.a - Variation Type IA - 2	B.II.b.2.a Replacement or addition of a site where batch control/testing takes place	Medical Device	B.II.b.2.a - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place
•	B.II.g.1.a - Variation Type II - 1	B.II.gI.a. One or more unit operations in the manufacturing process of the finished product including the resulting in- process controls and/or test procedures	Text / Org. Changes	B.II.g.j.a., QUALITY CHANGES - FINISHED PRODUCT - Design Space and poor approved change management protocol - Introduction of a new design space or extension of an approved design space for the inhished 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

Figure 50 - Selection of Scope and Identifier

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

#### NOTE:

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

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

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

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resent and Proposed Value(s) Selected Scope(s)	Selected Medicinal Product(s)			
Column visibility 🐱			Filter	c
Troduct Name	MRP / CP Number	MA Number	Authorisation Country	PMS Id
			European Union	
			European Union	
howing 1 to 2 of 2 entries 1 row selected				
elected Packaged Medicinal Product(s)				
Column visibility 🐱			Filter	
MA Number	MRP / CP Number	PMS ID	Pack Size	Authorisat Status
				Valid
				Valid
2				Valid
2				Valid
				Valid
ave Close				

Figure 51 - Selection of Products and MA

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.

Present and Proposed Changes				
Please add a Present and Proposed change f	for each Scope and Medicinal Product combination. A product ar	ea will be recommended based on your scope selection	. In addition to free text / Organisati	on changes, please check if structured
product data needs to be updated.		Proposed Change	✓ Search	Q Add Present/Proposed
	Scope(s)	Proposed Change Recommended Change(s)		Q Add Present/Proposed

Figure 52 - Add Present/Proposed Changes

## 2.5.2.3. Organisation Details

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

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



- 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

$\odot$	npleted 😣 osed Changes >	Present and P	roposed Value	(5)								==		
8	Present and Propos	ed Value(s) Si	elected Scope(s)	Selected Medicinal	Product(s)									
∽\$	Present *							Proposed *						
Ē	Enter text							Enter text						
ं														
Ø		- Size - B	Ι <u>U</u> <i>L</i> • Δ·	. = =	" ≣ ≣ ≣	ବତ୍ୟ ଅ		I Font	• Size • B	Ι <u></u>	= =	" Ξ Ξ Ξ	ବତ୍ତ୍ୟ, ପ	
$\bigotimes$	Organisation Det	ails									Do	this step f	first 📘	Add
	Organisation No t Selectable ↑	Organisation Na me (Present Or ganisation)	Organisation Lo cation (Present Organisation)				Modified On (Pr esent Organisati on)			Organisation Id (Proposed Orga nisation)	Full address (Pr oposed Organis ation)	Parent Organisa tion ID (Propos ed Organisatio n)	Modified On (Pr oposed Organis ation)	
	Yes							Catalent Indiana L LC	LOC-100025094	ORG-100016312	1300 South Patter son Drive Bloomin gton, IN 47403-4 828 United States	Catalent Indiana L LC	18/07/2022 01:0 7	•
	In case no OMS	selection is done, I de	clare this change doe	is not affect organisal	tions unless the organ	isation is being dele	ted							
	Save Close													

Figure 53 - Present and Proposed Value(s)

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



$\odot$	Pending X Proposed Changes > View/Propose Changes > Add / Edit Org
<i>0</i>	Organisation Not Selectable ①
ିକ ୦୦,	Present Organisation *
ं	Proposed Organisation *
Ø	٩
$\otimes$	
	Save Close

Figure 54 - Proposed Changes - Add/Edit Organisation

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

$\cong$ All Active Locations $\star$				Search
Phoose one record and click Select to continue ✓ Organisation Name ↑	Full address	Organisation Id	Organisation Location	Status
				Active





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

Proposed Cha	anges > View/Propose Chang	es > Add / Edit Org	
Drganis	ation Not Selectable ①	1	
Present Or	Organisation Not Selectable The organisation is not selectable as 1) the organisation no longer exists, or 2) there is a change in organisation name which does not		
	affect the address Figure 56 - Organisation Not S	Gelectable	

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 *

Figure 57 - Data of Not Selectable Organisation

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



$\mathbf{\mathfrak{O}}$	Pending 🛛 🛣 Proposed Changes > View/Propose Changes > Add / Edit Org	E
Ø	🖬 Organisation Not Selectable ①	
℃\$	Organisation Name *	City/Locality/Town/Village *
Ē	Address Line 1 *	Postcode
<u> </u>	Address Line 3	County
<u> </u>	Address Line 4	Country *
2	Proposed Organisation *	۹.
$\otimes$	<u>م</u>	
	Save	

Figure 58 - Proposed Organisation

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

osed Changes > View/Propose Changes > Add / Edit Org		🗁 KP 18
Organisation Not Selectable ①		
Present Organisation * European Medicines Agency × Q	Org ID ORG-100006175	LOC ID
	Address 30 Churchill Place London E14 SEU United Kingdom	Modified On 17/07/2022 22: Status * Active
Proposed Organisation * European Medicines Agency X Q	Org ID ORG-100013412 Address Orlypelin 24 Amsterdam 1043 DP Netherlands	LOC ID LOC-10001879 Modified On 12/09/2022 19:
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.

				1								
resent and Propo	ed Value(s)	Selected Scope(s)	Selected Medicin	al Product(s)								
Present *							Proposed *					
Enter text							Enter text					
I Font	- Size - B	I U 2-1	4. ≡ (= .= .		≣ ବଧ୍ୟ, I		I Font	- Size - B	I U 2- A	. = = .= .=		∎ @ ⊘ ∎
							V					
							•					
							•					
Organisation De	ails						•					
Organisation De	ais				Parent Organis		•				Parent Organis	
Organisation De Organisation N ot Selectable ↑	Organisation N ame (Present O rganisation)	Organisation Lo cation (Present Organisation)	Organisation Id (Present Organi sation)	Full address (Pr esent Organisat ion)	ation ID (Prese	Modified On (Pr esent Organisat ion)	Organisation N		Organisation Id (Proposed Orga nisation)			Modified On (1
Organisation N	Organisation N ame (Present O	cation (Present Organisation)	(Present Organi sation)	esent Organisat	ation ID (Prese nt Organisatio n)	Modified On (Pr esent Organisat ion) 17/07/2022 22:0	Organisation N ame (Proposed Organisation)	Organisation Lo cation (Propose d Organisation)	(Proposed Orga	Full address (Pr oposed Organis	Parent Organis ation ID (Propo sed Organisatio	Modified On (I oposed Organ ation)
Organisation N ot Selectable ↑	Organisation N ame (Present O rganisation) European Medicin es Agency	cation (Present Organisation)	(Present Organi sation) ORG-100006175	esent Organisat ion) 30 Churchill Place London E14 5EU United Kingdom Beethovenstrasse	ation ID (Prese nt Organisatio n) [ INACTIVE ] Eur opean Medicines Agency	Modified On (Pr esent Organisat ion) 17/07/2022 22:0 7 12/09/2022 14:0	Organisation N ame (Proposed Organisation) European Medicin es Agency	Organisation Lo cation (Propose d Organisation) LOC-100018793	(Proposed Orga nisation) ORG-100013412	Full address (Pr oposed Organis ation) Orlypiein 24 104 3 DP Amsterdam Netherlands	Parent Organis ation ID (Propo sed Organisatio n) European Medicin es Agency Austrian Agency	Modified On (i oposed Organ ation) 12/09/2022 19: 9 12/09/2022 14:
Organisation N ot Selectable ↑ No No	Organisation N ame (Present O rganisation) European Medicin es Agency Austrian Agency For Health And Fo od Safety	cation (Present Organisation) LOC-100010800 LOC-100000001	(Present Organi sation) ORG-100006175 ORG-100003912	esent Organisat ion) 30 Churchill Place London E14 SEU United Kingdom Beethovenstrasse 6 8010 Graz Aust ria	ation ID (Prese nt Organisatio n) [ INACTIVE ] Eur opean Medicines Agency Austrian Agency For Health And Fo od Safety	Modified On (Pr esent Organisat ion) 17/07/2022 22:0 7 12/09/2022 14:0 9	Organisation N ame (Proposed Organisation) European Medicin es Agency Austrian Agency For Health And Fo	Organisation Lo cation (Propose d Organisation) LOC-100018793	(Proposed Orga nisation) ORG-100013412	Full address (Pr oposed Organis ation) Orlyplein 24 104 3 DP Amsterdam Netherlands Traisengase 5 Br igitenau 1200 Vi	Parent Organis ation 10 (Propo sed Organisatio n) European Medicin es Agency Austrian Agency For Health And Fo	Modified On (i oposed Organ ation) 12/09/2022 19: 9 12/09/2022 14:
Organisation N ot Selectable ↑ No No	Organisation N ame (Present O rganisation) European Medicin es Agency Austrian Agency For Health And Fo	cation (Present Organisation) LOC-100010800 LOC-100000001	(Present Organi sation) ORG-100006175 ORG-100003912	esent Organisat ion) 30 Churchill Place London E14 SEU United Kingdom Beethovenstrasse 6 8010 Graz Aust ria	ation ID (Prese nt Organisatio n) [ INACTIVE ] Eur opean Medicines Agency Austrian Agency For Health And Fo od Safety	Modified On (Pr esent Organisat ion) 17/07/2022 22:0 7 12/09/2022 14:0 9	Organisation N ame (Proposed Organisation) European Medicin es Agency Austrian Agency For Health And Fo	Organisation Lo cation (Propose d Organisation) LOC-100018793	(Proposed Orga nisation) ORG-100013412	Full address (Pr oposed Organis ation) Orlyplein 24 104 3 DP Amsterdam Netherlands Traisengase 5 Br igitenau 1200 Vi	Parent Organis ation 10 (Propo sed Organisatio n) European Medicin es Agency Austrian Agency For Health And Fo	Modified On (i oposed Organ ation) 12/09/2022 19: 9 12/09/2022 14:
Organisation N ot Selectable ↑ No No	Organisation N ame (Present O rganisation) European Medicin es Agency Austrian Agency For Health And Fo od Safety	cation (Present Organisation) LOC-100010800 LOC-100000001	(Present Organi sation) ORG-100006175 ORG-100003912	esent Organisat ion) 30 Churchill Place London E14 SEU United Kingdom Beethovenstrasse 6 8010 Graz Aust ria	ation ID (Prese nt Organisatio n) [ INACTIVE ] Eur opean Medicines Agency Austrian Agency For Health And Fo od Safety	Modified On (Pr esent Organisat ion) 17/07/2022 22:0 7 12/09/2022 14:0 9	Organisation N ame (Proposed Organisation) European Medicin es Agency Austrian Agency For Health And Fo	Organisation Lo cation (Propose d Organisation) LOC-100018793	(Proposed Orga nisation) ORG-100013412	Full address (Pr oposed Organis ation) Orlyplein 24 104 3 DP Amsterdam Netherlands Traisengase 5 Br igitenau 1200 Vi	Parent Organis ation 10 (Propo sed Organisatio n) European Medicin es Agency Austrian Agency For Health And Fo	Modified On (i oposed Organ ation) 12/09/2022 19: 9 12/09/2022 14:

Figure 60 - Present and Proposed Value(s)

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





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

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

	Manageme	ecycle nt Portal	A Home Pr	oducts Management Service +   ePL +   Application For	ns • Forum SPOR • LAM Noel Diamant •
Ì	Pending X Proposed Changes			Variation Form	Human / Version: 1.110 / Application for variation to a marketing authorisation Demo teat ND / VAR/23/972 🛃 Last Saved : 06/11/2023 14:22
<i>8</i> 6	Product Selection Pending	Precise Scope and Background for Change	D		>
ぷ	Type(s) of Change(s) Pending	Present and Proposed Changes			^
	Procedural Information Pending	Hease add a Present and Proposed change for each Scop structured product data needs to be updated. Proposed Change	e and Medicinal Product combination. A product	rrea will be recommended based on your acope selection. In addit	lion to free text / Organisation changes, please check if Add Pressel/Proposed
Ċ	Proposed Changes	□ Product MA Number(s) ↑	Scope(s)	Recommended Change(s)	rod Proposed Change(s)
0	Finalisation Pending	There are no records to display.			
		Other Applications ®			>

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

	Product Lifecycle Management Portal	Products Management Service •   ePE •   Application Forme •   Forum   SPOR •   LAM   Noel Diamont •
Ì	Pending 🗍 Proposed Changes > Present and Proposed Value(s)	Variation Form Human / Vension: 1.110 / Application for variation to a marketing authoritation C Deno text NO / VVM(23/972 🕁 Last Sevid : 06/11/2023 14:22
8	Present and Proposed Value(s) Selected Scope(s) Selected Hedicinal Product(s)	
Х,	Present *	Proposed *
E	Enter hot.	From test
٢		
$\otimes$		$\phi' \mid fore  * \mid Sos \ast \land B  I  \cup  \mathscr{L} \ast  \underline{\wedge} \ast \equiv \ = \ \Rightarrow \ es \ \ast \equiv \ \equiv \ \Rightarrow \ \diamond_{1} \ s$
	EU ar National AOHF reference number (Present Org) ()	EU or National ASHF reference number(Proposed Crg) ()

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

I.

	9			
EUROPEAN				
SCIENCE	MEDICIN	ES	ΗΕΑ	LTH

	25	Add Package					×	4
		normal in Transformer Co	Parent Medicinal Product *					Р
	E		5.			Ÿ		S I d
	0		MA Number *		Pack Size *			
	Ċ							
	$\otimes$							
			Submit					
		G THA Number	400.7	P Number	PMS 10	Pack Size	Authori	sation
		C MA NUMBER	- RKP-7.5		ta available in table	Pace size	Status	
		howing 3 antrias						
•	_							
- 2****	Product	Lifecycle nent Portal		Home Products Managem	ent Service -   ePL -   Apr	plication Forms - Forum SPOR - 1	AM Noel Diamant -	
See.	Manager	ment Portal						
	ng ↓ posed Changes →	Present and Proposed Va	luc(s)		Va	viation Form Human / Version: 1.110 / Application for Demo test ND / VAR/23/972	variation to a marketing authorisation	
00	Present and Proposed	Value(s) Selected Scope(s)	Selected Medicinal Product(s)					
<b>_</b> \$	Column visit	bility v				Filter	٩	
	t.						p M	
e	Product Nan	ne -	MRP / CP Number	HA Numbe	r	Authorisation Country	s 1 d	
2				No data evallable in table				
õ								
$\bigotimes$	Showing <b>0</b> to <b>0</b> of <b>0</b> e	tries						
	Selected Packaged I	Aedicinal Product(s)						
	Column visit	siity v				filter	Q. Add Package	
		or -	MRP / CP Number	PMS ID		Pack Size	Authorisation Status	

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

## 2.5.3.1. Multiple change

#### 2.5.3.1.1. Duplicating the Present and Proposed fields

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



### 2.5.3.1.2. Linking of the organisations to the text changes

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

#### 2.5.3.2. Structured changes

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

#### 2.5.3.3. Medical Device(s)

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

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



Figure 62 - Medical Device Box

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



Present and Proposed Changes			^
Please add a Present and Proposed change for updated.	each Scope and Medicinal Product combination. A product area wil	II be recommended based on your scope selection. In addition to free text / Organis Proposed Change	aation changes, please check if structured product data needs to be Search Q Add Present/Proposed
Product MA Number(s) ↑	Scope(s)	Recommended Change(s)	Proposed Change(s)
There are no records to display.			

Figure 63 - Add Present/Proposed Changes

#### 3. Select the scope and the medicinal product/presentations

<i>8</i> 6	Present and Proposed Value(s) Selected Scope(s)	Selected Medicinal Product(s)			
X;	Column visibility v			Filter	
	Identifier	↑ 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 - QUALITY CHANGES - Medical Devices - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	
õ					
<i>(</i> 2,	Save Close				
$\odot$	Showing 1 to 1 of 1 entries				
	Figure 64 - Selected Scope(s)				

Figure 64 - Selected Scope(s)

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

Present and Proposed Changes				^
Please add a Present and Proposed change f please check if structured product data need	or each Scope and Medicinal Product combination. A p Is to be updated.	product area will be recommended based on your	scope selection. In addition to free text /	Organisation changes, Add Present/Proposed
Product MA Number(s) ↑ EU/1, 1	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	Proposed Change	e(s)

Figure 65 - Selection of relevant scope/product combination

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



Selected Scope(s)          Vedical Devices         Present Values         Device Name         Proposed Values         Refresh         O         Device Name         Perent Medicinal Product         Image: Comparison of the state service in table	osed Changes > Present & Proposed Medical De	evice	
Medical Devices   Present Values   Device Name   Preposed Values   Proposed Values   Proposed Values   Device Name   Proposed Values   Contraction of Contra			
Medical Devices   Present Values   Device Name   Preposed Values   Proposed Values   Proposed Values   Device Name   Proposed Values   Contraction of Contra			
Medical Devices   Present Values   Device Name   Preposed Values   Proposed Values   Proposed Values   Device Name   Proposed Values   Contraction of Contra			
Present Values   Device Name     Proposed Values   Refresh     Proposed Values   Refresh   Device Name     Proposed Values     No data available in table     No data available in table	✓ Selected Scope(s)		
Present Values   Device Name     Proposed Values   Refresh     Proposed Values   Refresh   Device Name     Proposed Values     No data available in table     No data available in table			
Present Values   Device Name     Proposed Values   Refresh     Proposed Values   Refresh   Device Name     Proposed Values     No data available in table     No data available in table	be the law of		
Device Name Parent Hedicinal Product     In o data available in table     Proposed Values     Refresh     Device Name     Parent Hedicinal Product   No data available in table   In o data available in table	Medical Devices		
Device Name Parent Hedicinal Product     In o data available in table     Proposed Values     Refresh     Device Name     Parent Hedicinal Product   No data available in table   In o data available in table			
howing 0 to 0 of 0 entries	Present Values		
howing 0 to 0 of 0 entries			
howing 0 to 0 of 0 entries  Proposed Values Refresh 2  Proposed Values Refresh 3  Proposed Values Refr	Device Name	Parent Medicinal Product	
howing 0 to 0 of 0 entries  Proposed Values Refresh 2  Proposed Values Refresh 3  Proposed Values Refr			
Proposed Values     Refresh     Ø       Device Name     Parent Medicinal Product   No data available in table		No data available in table	
Proposed Values     Refresh     Ø       Device Name     Parent Medicinal Product   No data available in table	Showing 0 to 0 of 0 entries		
Device Name     Parent Medicinal Product   No data available in table thowing 0 to 0 of 0 entries			
Device Name     Parent Medicinal Product   No data available in table thowing 0 to 0 of 0 entries			
Device Name     Parent Medicinal Product   No data available in table thowing 0 to 0 of 0 entries			
No data available in table	Proposed Values Refresh 2		Add Device Remove Association(s) Delete De
No data available in table			
No data available in table	O Device Name	Davant Medicinal Deeduct	
howing 0 to 0 of 0 entries		Parent Medicinal Product	
		No data available in table	
ave Cancel Delete Proposed Change	Showing 0 to 0 of 0 entries		
ave Cancel Delete Proposed Change			
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ave Cancel Delete Proposed Change			
ave Cancel Delete Proposed Change			
are carea Deeterripose charge	Saus Cancel Delate Prepared Change		
	Save Cancer Delete Proposed Change		

Figure 66 - Add Device

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

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

Figure 67 - Medical Device and Companion Diagnostic

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

Medical Device & Companion Diagnostic

Change to the design or intended purpose of the device component, or introduction of a new device / device constituent part uslv list on of the medical product. Please explain the purp se of a device cor nent previ ed in the marketing authorisati n of the medical produc

Figure 68 - Change Selection - Medical Device and Companion Diagnostic



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

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 *

Figure 69 - Device(s) Identification and Classification

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

Manufacturer of the device			^
Function *	٩		
Manufacturer *	٩		
Title *	First Name *	Last Name =	
Telephone	E-Mail		

Figure 70 - Manufacturer of the Device

#### 10. Proceed to fill in the rest of the sections

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

Figure 71 - Upload of Documentation

11. Notified body is also now selected from OMS

9
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Figure 72 - Notified Body

12. dsd

# 2.5.3.4. ATC Code change

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

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

Present and Proposed Changes				^
Please add a Present and Proposed change for please check if structured product data need:	or each Scope and Medicinal Product combination. A s to be updated.	product area will be recommended based on your Proposed Change	scope selection. In addition to free tex	t / Organisation changes, Add Present/Proposed
□ Product MA Number(s) ↑ ☑ 1	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	Proposed Char	nge(s)

Figure 73 - Present and Proposed Changes

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



oosed Changes >	Present & Proposed Pharmacothe	rapeuti	🗁 KP 19/09/22 Medical device test 🛛 / VAR/22/698 🛓 Last Saved :	: 19/09/
✓ Selected Sc	cope(s)			
Pharmacot	herapeutic Group (ATC)			
Present Values	5			
	<sup>®</sup> MA number	Product Name		
$\sim$	EU/1/21/1531	Evrysdi 0.75 mg/ml - Powder for oral solution		
Showing 1 to 1 of 1	entries			
			~~	1
Proposed Values			_	
				+
ATC Code ↑		Application for ATC code has been made		
There are no record	ds to display.			
Save Cancel	Delete Proposed Change			
Cunter	o and the posts change			

Figure 74 - ACT Code Change

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

Select ATC Code	×
FHIR Product ATC Code ATC code If it no ATC code has been axisgmed, please indicate if an application for ATC code has been made Source	C. Guidente Constanting Consta

Figure 75 - Selection of ATC Code

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

## 2.5.3.5. Pharmacovigilance System Master File

 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.



	e system master file			
Present Values				
J MA Number	Product Name	PSMF Code	PSMF Organization	The Pharmacovigilance system master file location has been registered in Article 57 database
Showing 1 to 1 of 1 entries				≪ 1
Proposed Values				
MF Organisation *		Q	PSMF Code *	
MF Organisation *		a		
ME Organisation *		q		
MF Organisation *		q		
MF Organisation *		a		
MF Organisation *		<u> </u>		
MF Organisation *		c		
	aster file location has been registered in Art			
The Pharmacovigilance system n		icle 57 database upplication form, a Qualified person Respo	nsible for Pharmacovigilance 'resides' in	the place where he/she makes his/her home, where he/she lives, can be traced, l

Figure 76 - Pharmacovigilance System Master File

Add the PSMF Organisation from the magnifying glass *Q* and the PSMF Code Click on the <u>Save</u> button and you will be taken back to the Proposed Changes main page Click on the <u>Save</u> button to save your changes in the form

# 2.5.3.6. 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.

9	
EUROPEAN MEDICINES AGENC	CY
SCIENCE MEDICINES HEALT	ΓН

	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 GMO: es	s? * ✓		
s the product comply with Directive 2	2001/18/EC2 *		

Figure 77 - Genetically Modified Organisms Code

**2.** Reply to the GMO-related enquiries

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

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

#### 2.5.4. Other applications

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

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.

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

Figure 79 - Additional Information Section

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

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

Type IB and Type II variations - new indications - orphan medicinal product information	^
Has orphan designation been applied for, for this new indication? O Ng 🖲 Yes Select Orphan Designation Procedure	٩

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

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 Remo	ove value

#### Figure 81 - Lookup Records

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



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

Figure 82 - Selection of Procedure

## 2.6.2. Information relating to orphan market exclusivity

#### 2.6.3. Type IB and Type II Variations – Paediatric Requirements

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

Type IB and Type II vari	ations - Paediatric Requirements ()	1			^
C Article 8 of the paediatric reg C This application relates to a p C This application relates to pa C This application relates to pa A sicle 8 Procedure Type C This application relates to a r A sicle 8 New Indication C is protected by a supplement is protected by a patent which C This application relates to pa	tion applies to this variation application since. I addition does not apply to this application since. I additic studies included in a paediatric invest ediatric studies submitted according to Article previous/ongoing/parallel procedure which trig new indication for an authorised medicinal pro any protection certificate under Regulation (Ef h qualifies for the granning of the supplement ediatric studies included in a paediatric invest ediatric studies submitted according to Article	e. uthorisation (PUMA). gation plan. 45 or 46 of the paediatric regulati gered Article 8 requirement. duct which: c) No 469/2009. ary protection certificate. igation plan			+ Add
Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision	Agreed scope ↑	Agreed condition/indication
There are no records to displ	ay.				
Has this application been subject	t:Specific Waiver decision including the paedia at to PIP compliance verification?	tric Committee (PDCO) opinion an	d the Summary Report, is to be included in N	(odule 1.10)	+ Add
The compliance document	reference ↑				
There are no records to displ	ay.				

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

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



Select Paediatric Enti	tlement(s)			×
				Search Q
<ul> <li>Entitlement Number</li> </ul>	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision Agreed scope $\uparrow$	Agreed condition/indication
< 1 2 3 4 5 6 7 1	8 173 →			
Selected records				
				Add Cancel

Figure 84 - Selection of Paediatric Entitlement(s)

#### 2. Add the entitlement

Select Paediatric Enti	tlement(s)			×
				106 9
Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision Agreed scope $\uparrow$	Agreed condition/indication
Selected records				
				Add Cancel
				Add Cancel

Figure 85 - Addition of Paediatric Entitlement(s)

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

(Note: a copy of the PIP/Product-Specific Waiver decision including the paediatric Committee (PDCO) opinion and the Summary Report, is to be included in Module 1.10) Has this application been subject	Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision	Agreed scope ↑	Agreed condition/indication	
							٢
		ic Waiver decision including the paediat	tric Committee (PDCO) opinion and the	Summary Report, is to be included in N	1odule 1.10)		

Figure 86 - Recap Table of Paediatric Entitlement(s)

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

9
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
Create Compliance Document Reference ×
Number
Procedure Number
Save

*Figure 87 - Creation of Compliance Document Reference Number* 

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

Type II variations - Extended data exclusivity / market protection	^
Extended data exclusivity / market protection O Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 725/2004 (one year of market protection for a new indication). O Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication). O Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification). ® Not applicable	

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).

$\bigotimes$	Pending X		
0	Product Selection	Annexed documents (where appropriate)	>
∽\$	Type(s) of Change(s) Pending <u>X</u>	Declaration	>
Ē	Procedural Information	Proof of payment	>
	Pending X	Signatories	>
٢	Proposed Changes Pending X	Save Validate Cancel Export Finalise	
$\otimes$	Finalisation		

#### Figure 89 - Finalisation Process



## 2.7.1.Annexed documents (where appropriate)

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



## 2.7.2. Declaration of the applicant

Declaration of the applicant			^
I hereby submit a notification/application for the above Marketing A	uthorisation(s) to be varied in accordance with the proposals given a	pove. I declare that (Please tick appropriate declarations)	
Where applicable, national fees have been prepaid or will be particular to the pa	id in accordance with national requirements;		
For type IA notifications: the required documents as specified f	or the changes concerned have been submitted;		
	in RMS and all CMSs (for products within the Mutual Recognition Pri al Competent Authorities and/or RMS/ CMS (as applicable) and the E	cedure and worksharing) or both to EMA and (Co-)Rapporteur (for products w MA;	ithin the Centralised Procedure) o
$\square$ * There are no other changes than those identified in this appl	ication (except for those addressed in other variations submitted in g	arallel);	
For worksharing or grouped variations affecting more than one	MA: the MAs concerned belong to the same MAH.		
<ul> <li>Where applicable, all conditions as set for the variation(s) conc</li> </ul>	erned are fulfilled;		
Change(s) will be implemented from: *			
Next production run/next printing	Changes implementation date	Changes implementation comment	
	DD/MM/YYYY	<b>#</b>	

Figure 91 - Declaration of the Applicant

## 2.7.3. Proof of Payment

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

Proof of payment						^
Have all relevant fees been prepaid to c $\circledast$ No $~\bigcirc$ Yes (for the fees paid, attach						
Customer Purchase Order / Refer ence Number	Address / Billing address ↑ European Medicines Agency	Customer Account Number	Full Address Domenico Scarlattilaan 6 1083 HS A msterdam Netherlands	Telephone	E-Mail	۲





#### 2.7.4. Signatories

Signatories			
Main Signatory		Additional Signatory	
First Name *		First Name	
Sumame *		Sumame	
Status(Job Title) *		Status(Job Title)	
Date *		Date	
dd/mm/ yyyy	Ð	dd/mm/yyyy	₽
For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the	designi	ated contacts as specified in section 2.4.3 in Part IA/Module 1 Application Form for each of the MAs concerned.	

Figure 93 - Signatories

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

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

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



## 3. Exporting the form content to a PDF

## **3.1.** *PDF Export*

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

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

					▶ 18/09/2022 23:52:40 PM	
9 18/09/22 Q	uality Groupin	<b>g</b> var/22/649				
xport typically takes les	s than a minute but can tak	e longer to complete, depending on the size of	Fyour Application. You'll get an email to notify	you when the process is o	complete and ready to download.	
Export Started						
Column visibility Sh	iow 10 rows				Search	Q Refresh
Modified On	Created On	Requestor	Status Reason	FHIR PDF	Validation XML	Export Message
	19/09/2022 00:34:	Kristiina Puusaari	Active			
19/09/2022 00:34: 20 AM	20 AM					

Figure 94 - Preparation of Export

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

18/09/22 Q	uality Groupin	<b>g</b> VAR/22/649			▶ 18/09/2022 23:52:40 PM	
port 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	you when the process is	complete and ready to download.	
			Completed			
			Download 🛓			
Column visibility Sho	ow 10 rows				Search	٩
Column visibility Sho	ow 10 rows Created On	Requestor	Status Reason	FHIR PDF	Search Validation XML	Q Export Mess

Figure 95 - Export Completed

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

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



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.

ß	Attachments ×	_	
		L	
0	Name C eAF.xml		
	Name: eAF.xml Modified: 18/09/2022 21:23:06		
	Size: 880.61 KB	1	
			Generated: 2022-09-18 07:23:01 (UTC)
			TABLE OF CONTEN
			1. APPLICAT
			2. PRODUCT
		•	3. TYPES OF 4.a Type IB an
	Figure 07 E		

Figure 97 - FHIR xml

Figure 96 - Exported Form





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.



# Report an issue with PLM portal (eAF)

Request assistance on a PLM Portal - eAF issue.

	Create a ticket for the issue you are experiencing.	
	Before creating a new ticket, please double check the available guidance - the issue you are experiencing may be explained there.	
	PLM Portal – Human Variations eAF: Guide to registration	
	PLM Portal – Human Variations eAF: Guide to navigation PLM Portal – eAF   How to monitor Application Forms Status	
	PLM Portal - eAF   How to select the scope of the variation	
	application PLM Portal – eAF   How to fill in the "Procedural Information" section	'n
	PLM Portal – eAF   How to fill in the "Additional Information" sectio PLM Portal – eAF   How to fill in the "Finalisation" section	n
	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		
<ul> <li>Indicates required</li> <li>Raise this request on behalf of</li> <li>Kristiina Puusaari</li> </ul>	×	Ŧ
Raise this request on behalf of	×	Ŧ
Raise this request on behalf of Kristiina Puusaari	×	Ŧ
Raise this request on behalf of Kristiina Puusaari	×	Ŧ
Raise this request on behalf of Kristiina Puusaari Subject	×	v
Raise this request on behalf of Kristiina Puusaari Subject	×	· ·
Raise this request on behalf of Kristiina Puusaari Subject	*	*
Raise this request on behalf of Kristiina Puusaari Subject Description	×	
Raise this request on behalf of Kristiina Puusaari Subject Description	×	
Raise this request on behalf of Kristiina Puusaari Subject Description	×	
Raise this request on behalf of Kristiina Puusaari Subject Description Problem area Urgency	×	

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



# Request for information - PLM portal (eAF)

Request assistance on a PLM Portal - eAF issue

	Create a ticket for the issue you are experiencing.	
	Before creating a new ticket, please double check the available guidance - the issue you are experiencing may be explained there.	
	PLM Portal – Human Variations eAF: Guide to registration PLM Portal – Human Variations eAF: Guide to navigation PLM Portal – eAF   How to monitor Application Forms St PLM Portal – eAF   How to select the scope of the variat application PLM Portal – eAF   How to fill in the "Procedural Information	n tatus ion ation" section
	PLM Portal – eAF   How to fill in the "Additional Informa PLM Portal – eAF   How to fill in the "Finalisation" sectio	
	Please provide as much detail as possible (incl. step-by-st and/or screenshot(s) as attachments, if/when applicable). report an issue pertaining the filling of an electronic Appli Web-user interface / Data / Access / FHIR XML / PDF e Regulation / Other	Example: ication Form:
Indicates required		
Raise this request on behalf of Kristiina Puusaari		×
Subject		
Description		
Problem area		
Ø Add attachments		





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

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

## **4.4.** The PLM Chatbot

 $\bigcirc$ 

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.

Product Lifecycle Management Portal		in 🔥 Home   Forum   SPOR 👻   IAM   Sign in	
Welcome to PLM Portal A secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the European Union, in collaboration with the European Medicines Regulatory Network.		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.	
Sign In 🗲		Please choose one of the following topics:	
Quick links		Post-authorisation Help	
Public Register & 0 List 0 0	Guidance & O Support	Ne Type your message	
	Figure 101 - PLM Chatbot		