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Product Lifecycle Management Portal – Human Variations eAF

Guide to navigation

Version 1.2

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Contents

1. Pu	pose and Context٤	3
1.1.	Purpose of this guide	3
1.2.	Preliminary requirements	3
1.3.	Supported Browsers	3
2. Na	vigation through the PLM Portal - eAF9	•
2.1.	Creating an application form	Э
2.1.1.	How to access the PLM Portal - eAF	Э
2.1.2.	How to create a new electronic Application Form	Э
2.1.3.	How to access previously created/edited electronic Application Form(s)14	1
2.1.3.1.	Re-open `completed' form for further editing18	3
2.1.4.	Copy form function18	3
2.1.5.	Delete form function18	3
2.1.6.	How to add/delete co-authors from an Application Form	3
<mark>2.2.</mark>	Product Selection	Э
2.2.1.	How to add a product in an Application Form19	Э
2.2.2.	How to update the MRP Nr. of a product in an Application Form22	2
2.2.3.	How to delete a product from an Application Form	2
2.3.	Гуре(s) of change(s)24	1
2.3.1.	How to add a variation scope in an Application24	1
2.3.2.	How to delete a scope in an application29	Э
2.4.	Procedural Information	C
2.4.1.	Procedural Information)
2.4.2.	Name and Address of MA Holder (Applicant)	2
2.4.3.	Contact Person	3
2.5.	Proposed Changes	1
2.5.1.	Precise Scope and Background for Change	5
2.5.2.	Present and Proposed Changes	5
2.5.2.1.	Present and Proposed Text Changes	5
2.5.2.2.	How to map a product to a scope change in an Application Form	3
2.5.2.3.	Organisation Details40)
2.5.2.4.	Multiple change	5
2.5.2.4.1	Duplicating the Present and Proposed fields45	5
2.5.2.4.2 fields	Linking of the organisations to the text changes the Present and Proposed 46	
2.5.2.5.	Structured changes46	5
2.5.2.6.	Medical Device(s)46	5
2.5.2.7.	ATC Code change)
2.5.2.8.	Pharmacovigilance System Master File5	1
2.5.2.9.	Genetically Modified Organisms52	2



2.5.3.		Other applications	53
2.6.	Additio	onal Information	54
2.6.1. informat	ion	Type IB and Type II Variations – new indications – orphan medicinal produ 54	ct
2.6.2.		Information relating to orphan market exclusivity	55
2.6.3.		Type IB and Type II Variations – Paediatric Requirements	55
2.6.4.		Type II Variations – Extended data exclusivity / market protection	57
2.7.	Finalis	ation	57
2.7.1.		Annexed documents (where appropriate)	58
2.7.2.		Declaration of the applicant	58
2.7.3.		Proof of Payment	58
2.7.4.		Signatories	59
3. Ex	portin	ig the form content to a PDF	50
3.1.	PDF E>	xport	60
3.2.	PDF Re	equirements	62
4. Su	ipport		53
4.1.	The PL	M Forum	63
	The C	prvice Deck	63
4.2.	The Se	er vice Desk	05

Table of Figures

Figure 1 - Sign-in
Figure 2 - New Application Form
Figure 3 - Application Form Type 10
Figure 4 - Application Details
Figure 5 - Reference MAH 11
Figure 6 - Create & Next Button 11
Figure 7 - Add Co-author
Figure 8 - My Organisation Affiliate(s)' Tab 12
Figure 9 - Add Co-author 13
Figure 10 - View/Manage Co-authors 14
Figure 11 - Add Co-author 14
Figure 12 - Application Forms 15
Figure 13 - List of Application Forms15
Figure 14 - Add Product
Figure 15 - List of Products 20
Figure 16 - View Available Products



Figure 17 - Packaged Medicinal Product(s) 21
Figure 18 - Save and Validate Buttons 22
Figure 19 - Associate MRP Nr. Button 22
Figure 20 - Add Product 23
Figure 21 - View Available Products
Figure 22 - Add Scope 24
Figure 23 - Select Scope
Figure 24 - Example of Search using Classification Code
Figure 25 - Example of Search using Wild Card and Text
Figure 26 - Cancel and Select Scope
Figure 27 - Select Procedure Type
Figure 28 - Select Procedure Type
Figure 29 - Option Selection
Figure 30 - Summary of Selection
Figure 31 - Add Scope
Figure 32 - Delete Scope
Figure 33 - Edit Scope
Figure 34 - Procedural Information Section Overview
Figure 35 - Sub-section: Procedural Information
Figure 36 - Variation Procedure Number
Figure 37 - Name and Address of MA Holder (Applicant)
Figure 38 - Contact Person
Figure 39 - Create Application Contact
Figure 40 - Lookup Records
Figure 41 - Proposed Changes
Figure 42 - Precise Scope and Background for Change
Figure 43 - Proposed Changes
Figure 44 - Present and Proposed Changes
Figure 45 - Present and Proposed Values
Figure 46 - Present and Proposed Values - Toolbar Options
Figure 47 - Selection of Scope and Medicinal Product
Figure 48 - Selection of Scope and Identifier
Figure 49 - Selection of Products and MA 40
Figure 50 - Add Present/Proposed Changes 40
Figure 51 - Present and Proposed Value(s)
Figure 52 - Proposed Changes - Add/Edit Organisation
Figure 53 - Select Present Organisation 42
Figure 54 - Organisation Not Selectable 43
Figure 55 - Data of Not Selectable Organisation



Figure 56 - Proposed Organisation 44
Figure 57 - Present and Proposed Section 44
Figure 58 - Present and Proposed Value(s) 45
Figure 59 - Pop-Up showing details inserted 45
Figure 60 - Medical Device Box 46
Figure 61 - Add Present/Proposed Changes 47
Figure 62 - Selected Scope(s) 47
Figure 63 - Selection of relevant scope/product combination
Figure 64 - Add Device
Figure 65 - Medical Device and Companion Diagnostic
Figure 66 - Change Selection - Medical Device and Companion Diagnostic
Figure 67 - Device(s) Identification and Classification
Figure 68 - Manufacturer of the Device
Figure 69 - Upload of Documentation
Figure 70 - Notified Body
Figure 71 - Present and Proposed Changes 50
Figure 72 - ACT Code Change
Figure 73 - Selection of ATC Code
Figure 74 - Pharmacovigilance System Master File 52
Figure 75 - Genetically Modified Organisms Code
Figure 76 - Selection of EMA Procedure
Figure 77 - Additional Information Section
Figure 78 - Orphan Designation Procedure
Figure 79 - Lookup Records
Figure 80 - Selection of Procedure
Figure 81 - Type IB and Type II Variations – Paediatric Requirements
Figure 82 - Selection of Paediatric Entitlement(s)
Figure 83 - Addition of Paediatric Entitlement(s)
Figure 84 - Recap Table of Paediatric Entitlement(s)
Figure 85 - Creation of Compliance Document Reference Number
Figure 86 - Type II Variations – Extended data exclusivity/market protection
Figure 87 - Finalisation Process
Figure 88 - Annexed Documents
Figure 89 - Declaration of the Applicant
Figure 90 - Proof of Payment
Figure 91 - Signatories
Figure 92 - Preparation of Export
Figure 93 - Export Completed
Figure 94 - Exported Form



Figure 95 - FHIR xml	. 61
Figure 96 - XML file - Document Tree	. 62
Figure 97 - Report an Issue with PLM Portal (eAF) Form	. 64
Figure 98 - Request for Information - PLM Portal (eAF) Form	. 65
Figure 99 - PLM Chatbot	. 66



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 this is an early version of this guide and it may contain errors and incomplete information

1.2. *Preliminary requirements*

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

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

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



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>

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

Product Lifecycle Management Portal	♠ Home Forum SPOR ✔ IAM Sign in
Product Lifecycle Management (PLM) Portal Portal for applicants to fill in and generate electronic Application Forms for European Regulatory Procedures and to update Product Data 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 - eAF guide for registration</u>

- **1.** Sign into the PLM Portal eAF
- 2. On the home page, click on "Application Forms" in the centre-left or in top navigation bar,

C Produ Mana	ict Lifecycle gement Portal	A Home	Application Forms 👻	Forum SPOR + IAM Kristiina Puusaari +
	Product Lifecycle Management (PLM) Portal Portal for applicants to fill in and generate electronic Application Forms for Regulatory Procedures and to update Product Data	European	Application Forms	
	Application Forms >			

Figure 2 - New Application Form

3. Click on New Application Form

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



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

In the 1. Select Application Details screen:

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

Select Application Form	Туре		×
		Search	۹
Choose one record and click Select to continue			
✓ Name ↑	Description	Domain	
Variation Form Human	Application for variation to a marketing authorisation	Human use	
		Select Cancel Remove v	alue

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

Home > Application Forms > Draft Application Form	
1 Select Application Details 2 Add Co-Author	
Application Form Type "	Friendly Name "
Variation Form Human	× Q KP 02/11/22 TestPill Type IA
Reference MAH ()"	
	Ŭ
Create & Next Cancel	

Figure 4 - Application Details

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.

Sel	ect Reference MAH			×
				LOC-100020260 Q
Choose	one record and click Select to continue			
~	Organisation Name 个	Full address	Organisation Id	Organisation Location
	European Medicines Agency	P. O. Box 71010 1008 BA Amste rdam Netherlands	ORG-100013412	LOC-100020260
			1	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.

Application Form Type *	Friendly Name *	
Variation Form Human	× Q KP 02/11/22 TestPill Typ	pe IA
Reference MAH ()*		
European Medicines Agency	<u>x</u>	
Org ID	LOC ID	
ORG-100013412	LOC-100020260	
Address	Customer Account Number	er
P. O. Box 71010 Amsterdam 1008 BA	_	
Netherlands	Modified On	
	13/09/2022 07:09	

Figure 6 - Create & Next Button

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.

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

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

SCIENCE

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

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

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

Info	have all products contained within this application includi	na commercially confidential information a	nd product data from SPOR Product Managem	ent System (PMS)
Adding an applicant contributor will System (PMS).	Il share all products contained within all applications of th	is organisation including commercially con	idential information and product data from SF	OR Product Management
575tan (11157)				
				(i) Add Co-author
Full Name	Contact Email	Role 🛧	Role Status	
Kristiina Puusaari	Kristiina.Puusaari@ema.europa.eu	EMA Admin Assistant	Affiliated	•

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.

California	and the w			Search En-authors	9
0	Eal Name	14	Balle	Great	
	and on the second se		Applicant Hanager	Contraction (Contraction)	í
0	12. a. () = 28.		Applied Acoust	Carlos Paran	
	20010000		Applace measure	Contraction of the second	
0	20200000		Applicant Hansper	100000	
0	1000 C 1000		Applicant Constitution	The second second	
6	1.000		Applied Hanager	Contraction (Theorem	
	2020000		Applicant Hampier	Contraction of the local distance of the loc	





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.

Automated notifications are **not 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.

Home > Application Forms > Draft Application Form > Add Co-a	uthor							
Info Adding an applicant Manager will share all products contained within this application including commercially confidential information and product data from SPOR Product Management System (PMS). Adding an applicant contributor will share all products contained within all applications of this organisation including commercially confidential information and product data from SPOR Product Management System (PMS).								
From My Organisation Affiliate(s) From Other Organisation(s)	From My Organisation Affiliate(s) From Other Organisation(s)							
Search User by E-Mail ema.eu								
Full Name	Contact E-Mail							
	a.europa.eu							
Save								

Figure 9 - Add Co-author

Those users whose Role Status is '**Pending**' should receive a notification e-mail asking for the submission of an access role request for that organisation.

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



Product Manage	Lifecycle ment Portal			📌 Home	Application For	ms ← Forum	SPOR -	IAM 📔 Kristiina Puusaari 👻
Home > Application F	orms ed Completed All		Column visibility 🗸 Re	fresh 😂 Download	B	puu	٩	+ Create New Application Form
Application Form Id	↑ Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	UModified On (Access Date)	Status
	KP 02/11/22 TestPill Type IA	Variation Form Human	European Medicines Agency	Kristiina Puusaari	02/11/2022 10:59	Kristiina Puusaari	02/11/2022 11:01	Draft
	KP 02/11/22 grouping	Variation Form Human		Kristiina Puusaari	02/11/2022 08:14	Kristiina Puusaari	02/11/2022 10:33	Edit Application Form Exports Deactivate Application Form
	KP 02/11/22 restest co- author	Variation Form Human	European Medicines Agency	Kristiina Puusaari	02/11/2022 10:18	Kristiina Puusaari	02/11/2022 10:28	Copy Application Form View/Manage Co-authors
-	KP 02/11/22	Variation	European Modicines Agency	Kristiina	02/11/2022	Kristiina	02/11/2022	Draft 💿

Figure 10 - View/Manage Co-authors

Home	> Application Forms > View/Manage Co-A	uthor							
(i)	Info Adding an applicant Manager will share all products contained within this application including commercially confidential information and product data from SPOR Product Management System (PMS). Adding an applicant contributor will share all products contained within all applications of this organisation including commercially confidential information and product data from SPOR Product Management System (PMS).								
				(i Add Co-author				
	Full Name	Contact Email	Role ↑	Role Status U Pending					
	Kristiina Puusaari	Kristiina.Puusaari@ema.europa.eu	EMA Admin Assistant	Affiliated	٢				
	llose								

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.

- **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



Product Lifecycle Management Portal	e Application Forms ┣ Forum SPOR ▾ IAM Kristiina Puusaari ▾
	Application Form
Product Lifecycle Management (PLM) Portal	
Portal for applicants to fill in and generate electronic Application Forms for Europe Regulatory Procedures and to update Product Data	an E
Application Forms >	

Figure 12 - Application Forms

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

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

Produc Manag	t Lifecycle ement Portal			📌 Home	Application For	rms 👻 📔 Forum	SPOR 🗸	IAM Kristiina Puu	usaari 👻
Home > Application	Forms		Column visibility 🗸 Re	efresh 💋 Downlo	ad 🖪	Search	٩	+ Create New Ap	plication Form
Application Form Id	\uparrow Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	↓ Modified On (Access Date)	Status	
VAR/22/88	business scenario 5	Variation Form Human			01/11/2022 15:44		02/11/2022 11:11	Draft	
VAR/22/103	KP 02/11/22 TestPill Type IA	Variation Form Human			02/11/2022 10:59		02/11/2022 11:01	Edit Application Form Exports Deactivate Application	1 Form
VAR/22/92	KP 02/11/22 grouping	Variation Form Human			02/11/2022 08:14		02/11/2022 10:33	Copy Application Form View/Manage Co-auth	n nors
VAR/22/102	v6	Variation Form Human			02/11/2022 10:21		02/11/2022 10:31	Draft	
VAR/22/101	KP 02/11/22 restest co- author	Variation Form Human			02/11/2022 10:18		02/11/2022 10:28	Draft	
VAR/22/100	v6	Variation Form Human			02/11/2022 10:07		02/11/2022 10:08	Draft	٢
VAR/22/99	v5	Variation Form Human			02/11/2022 10:05		02/11/2022 10:05	Draft	٢

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.

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	(UAT) eAF Applicant Contributor	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	(UAT) eAF Competent Authority User
			_	
Draft	- Edit Application Form	- Edit Applicati	on Form	
	- Exports	- Exports		
	- View/Manage Co-authors	- Deactivate A	pplication Form	
		- Copy Applica	tion Form*	
		- View/Manage	e Co-authors	
Deactivated	- View Application Form	- View Applicat		
	- View Co-authors	- View Co-auth	ors	
	- Exports	- Exports		
		- Copy Applica	tion Form*	
		- Reopen Appli	cation Form	
		- Delete Applic	ation Form*	
Completed	- View Application Form	- View Applicat	tion Form	
	- View Co-authors	- View Co-auth	nors	
	- Exports	- Exports		
		- Reopen Appli	cation Form	

Table 1 - Application Form operations



User	Industry (NCA user(s)				
		- Copy Application Form*				
		- Deactivate Application Form				
All	Operations depend on the Status of the Application Form.					
	Refer to the above operations and statuses					
*	Feature not currently working					

Description of the different operations:

- Exports it generates a FHIR PDF file, FHIR standards complaint, and a Validation XML file, containing encountered errors in the selected Application Form as it has been filled in,
- View Co-authors it provides a (read-only) list of all previously added co-authors onto a given Application Form;
- View/Manage Co-authors it provides a list of all previously added co-authors onto a given Application Form, allowing to manage that list (delete and/or notify co-authors) and to add new co-authors. If at least one co-author has been added, you may also remove yourself. In that case, you would lose access to that Application Form and would no longer be able to see/edit it.
- View Application Form it provides a (read-only) view of that Application Form in terms of Product Selection, Type(s) of change(s), Procedural Information, Proposed Changes and Finalisation;
- Edit Application Form to enter into that Application Form and insert/update its details;
- Copy Application Form it creates a separate copy of that Application Form (please note that this feature is currently **not available**);
- Deactivate Application Form it updates the Application Form status to Deactivated. Marking Application Form with the Deactivated status works as an intermediate soft deletion deactivated Application Forms can always be moved back to Draft status, edited, finalised, and get Completed status or be completely deleted (the delete function is not currently available). Application Forms with Deactivated status have a retention time of one year after that time, if the Application Form creator does not reopen or finalise it, that Application Form will be completely deleted. A notification e-mail will be sent to the Application Form creator seven days before the end of the retention period;
- Reopen Application Form it updates the Application Form status to Draft, allowing editing on that same Application Form;
- Delete Application Form it completely deletes the Application Form so that it will no longer be possible to see/access it. Note: this feature is currently **not available** – when 'delete application form' is clicked, the form moves back under the 'Draft' tab.

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



While the Copy Application Form feature is not yet available, it may be tempting to edit previously created application form (that has been already submitted for a different procedure), especially if the form contains the same products and similar scopes, for a purpose of using this form for another procedure. Please note that if you make changes to a form that has been previously submitted for another procedure and are subsequently asked by the EMA to update the form during business validation/during the ongoing procedure for the originally submitted variation, you will need to make further edits to ensure that the originally provided information hasn't changed and only the requested changes have been made.

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' 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 (the form that has been finalised and submitted to the regulator) can be reopened for editing by clicking the small arrow in the right hand corner in the list of forms (completed tab)

Produ Mana	uct Lifecycle Igement Portal				A Home Produ	ts Data Management + Application	Forms - Forum 1	POR - I JAM	Kristina Puusaari +
me > Application Forms									
Draft Deactivated	Completed All Col	umn visibility 🗸 Refresh 🖉 Dovinload 🛙						٩	 Create New Application Form
Application Form Id	Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	Modified On (Access Date)	Status	
VAR/22/1570	business scenario 7	Variation Form Human			27/10/2022 11:19		27/10/2022 11:38	Completed	•
VAR/22/1568	business scenario 6	Variation Form Human			27/10/2022 11:03		27/10/2022 11:18	Completed	٥
VAR/22/1560		Variation Form Human			26/10/2022 13:56		26/10/2022 14:45	Complete Vie	« Application Form « Co-authors
VAR/22/1558	Business scenario 5	Variation Form Human			26/10/2022 12:32		26/10/2022 14:30	Completer Rec	orts pan Application Form
VAR/22/689	Misko test	Variation Form Human			19/09/2022 10:00		17/10/2022 15:53	Complete Cos	v Applicate Become Application

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 form function

The copy form function is currently not available

2.1.5. Delete form function

The delete form function is currently not available

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

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

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



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

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;

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.

- 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

Produc Manag	t Lifecycle ement Portal	Home	Application Forms Forum SPOR - IAM Kristiina Puusaari -
	Product Lifecycle Management (PLM) Portal		New Application Form
	Portal for applicants to fill in and generate electronic Application Forms for a Regulatory Procedures and to update Product Data	European	

Figure 12 - Application Forms

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

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

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EUROPEAN MEDICINES	AGENCY
SCIENCE MEDICINES	HEALTH

Product Manage	t Lifecycle ement Portal			🛖 Home	Application For	rms 👻 📔 Forum	SPOR 🗸 🛛	IAM Kristiina I	Puusaari 👻
Home > Application I	Forms		Column visibility 🗸 Re	fresh 💋 Downlo.	ad 🖪	Search	٩	+ Create New	Application Form
Application Form Id	↑ Friendly Name	Application Form Type	Reference MAH	Created By	Created On	Modified By (Last User)	UModified On (Access Date)	Status	
VAR/22/88	business scenario 5	Variation Form Human			01/11/2022 15:44		02/11/2022 11:11	Draft	
VAR/22/103	KP 02/11/22 TestPill Type IA	Variation Form Human			02/11/2022 10:59		02/11/2022 11:01	Edit Application For Exports	ion Form
VAR/22/92	KP 02/11/22 grouping	Variation Form Human			02/11/2022 08:14		02/11/2022 10:33	Copy Application Fo	uthors
VAR/22/102	v6	Variation Form Human			02/11/2022 10:21		02/11/2022 10:31	Draft	•
VAR/22/101	KP 02/11/22 restest co- author	Variation Form Human			02/11/2022 10:18		02/11/2022 10:28	Draft	۲
VAR/22/100	v6	Variation Form Human			02/11/2022 10:07		02/11/2022 10:08	Draft	•
VAR/22/99	v5	Variation Form Human			02/11/2022 10:05		02/11/2022 10:05	Draft	۲

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.

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 \checkmark , 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	Ind	NCA user(s)	
Role name	(UAT) eAF Applicant		

	9	
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SCIENCE	MEDICINES	HEALTH

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

Description of the different operations:

- Exports it generates a FHIR PDF file, FHIR standards complaint, and a Validation XML file, containing encountered errors in the selected Application Form as it has been filled in,
- View Co-authors it provides a (read-only) list of all previously added co-authors onto a given Application Form;
- View/Manage Co-authors it provides a list of all previously added co-authors onto a given Application Form, allowing to manage that list (delete and/or notify co-authors) and to add new co-authors. If at least one co-author has been added, you may also remove yourself. In that



case, you would lose access to that Application Form and would no longer be able to see/edit it.

- View Application Form it provides a (read-only) view of that Application Form in terms of Product Selection, Type(s) of change(s), Procedural Information, Proposed Changes and Finalisation;
- Edit Application Form to enter into that Application Form and insert/update its details;
- Copy Application Form it creates a separate copy of that Application Form (please note that this feature is currently **not available**);
- Deactivate Application Form it updates the Application Form status to Deactivated. Marking Application Form with the Deactivated status works as an intermediate soft deletion deactivated Application Forms can always be moved back to Draft status, edited, finalised, and get Completed status or be completely deleted (the delete function is not currently available). Application Forms with Deactivated status have a retention time of one year after that time, if the Application Form creator does not reopen or finalise it, that Application Form will be completely deleted. A notification e-mail will be sent to the Application Form creator seven days before the end of the retention period;
- Reopen Application Form it updates the Application Form status to Draft, allowing editing on that same Application Form;
- Delete Application Form it completely deletes the Application Form so that it will no longer be possible to see/access it. Note: this feature is currently **not available** – when 'delete application form' is clicked, the form moves back under the 'Draft' tab.

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

While the Copy Application Form feature is not yet available, it may be tempting to edit previously created application form (that has been already submitted for a different procedure), especially if the form contains the same products and similar scopes, for a purpose of using this form for another procedure. Please note that if you make changes to a form that has been previously submitted for another procedure and are subsequently asked by the EMA to update the form during business validation/during the ongoing procedure for the originally submitted variation, you will need to make further edits to ensure that the originally provided information hasn't changed and only the requested changes have been made.

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

2.2.1.1. Re-open 'completed' 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 (the form that has been finalised and submitted to the regulator) can be reopened for editing by clicking the small arrow in the right hand corner in the list of forms (completed tab)



Produ Mana	ict Lifecycle gement Portal				🕐 Home 🔰 Produ	cts Data Management + Appl	ication Forms + Forum 1	POR - IAM Kristina Puusaari -
ome > Application Forms								
Draft Deactivated	Completed All Col	umn visibility 🗸 Refresh 🖨 Dovinioad	b					Q, + Create New Application For
Application	200 B	Application		-		Modified By	Modified On	
Form Id	Friendly Name	Form Type	Reference MAH	Created By	Created On	(Last User)	(Access Date)	Status
VAR/22/1570	business scenario 7	Variation Form Human			27/10/2022 11:19		27/10/2022 11:38	Completed
VAR/22/1568	business scenario 6	Variation Form Human			27/10/2022 11:03		27/10/2022 11:18	Completed
VAR/22/1500		Variation Form Human			26/10/2022 13:56		26/10/2022 14:45	Complete View Application Form
VAR/22/1558	Business scenario 5	Variation Form Human			26/10/2022 12:32		26/10/2022 14:30	Completer Reopen Application Form
VAR/22/689	Miske test	Variation Form Human			19/09/2022 10:00		17/10/2022 15:53	Completer Copy Applicate Texas

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

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

2.2.2. Copy form function

The copy form function is currently not available

2.2.3. Delete form function

The delete form function is currently not available

2.2.4. How to add a product in an Application Form

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

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

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

- 1. Access an existing or create a new Application Form. See sections 2.1.1, 2.1.2 and 2.1.3 for further details
- 2. In the Product Selection page, as a first step in a new application form click on + Add Product button.

Please note that the 'search' field with the magnifying glass \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.

Ø	Product Selection Pending	Products concerned by this application ① Column visibility v Show 10 rows Refresh 2 Associate MRP Nr. Search Q + Add Prod											
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 Pending	Showing	1 0 to 0 of	0 entries		N	o data availabl	e 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.

<i>8</i> 6	Pending Produc	∑ t Selectior	ı → View / Sele	ect Product		•			Variati	on Form Human / Version	: 1.0.0.0 / Application for I Type IA / VAR/22/103	variation to a marketing autho	orisation 22 12:01
Ø		Column visi	ibility v Refresh	2 View Selected	Products							Search My Products	م
X\$		•	↑ Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI	
F			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 ^e 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						
	Showi Sav	ng 1 to 7 of 3,1 e Cancel	143 entries										

Figure 15 - List of Products

Click on <u>View Selected Products</u> to have a glance at the products you have selected in the previously. You may switch between that view and the <u>View Available Products</u> view to go back to the full list of selectable products.



	¹ Full Name	Authorised Dose Form	Active substance(s)	Authorisatio Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
2										
2										
5										

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



Ful Nai	ll ime	Authorised Dose Form	Active Substance	Authorisatio Country	n MA Holder	MA Nr.①	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
Arb ml inje	xtra 1.5 mg/0.3 - Solution for ection	Solution for injection	Fondaparinux sodium	European Union	Mylan IRE Healthcare Limited	EU/1/02/206	EMEA/H/C/000403	60000000045	60000000045		0/7
 Selecte	ed Packaged Medicin	al Product(s)								Search	
	Full Name		Pack Size	P	1A Number	MRP /	CP Number	PMS ID	Authorisatio Status	on	
	Arixtra 1.5 mg/0.3 for injection	ml - Solution	10 pre-filled sy	ringes E	U/1/02/206/025				Valid		
	Arixtra 1.5 mg/0.3 for injection	ml - Solution	10 pre-filled sy	ringes E	U/1/02/206/007				Valid		
	Arixtra 1.5 mg/0.3 for injection	ml - Solution	2 pre-filled syri	nges E	U/1/02/206/024				Valid		
	Arixtra 1.5 mg/0.3 for injection	ml - Solution	20 pre-filled sy	ringes E	U/1/02/206/026				Valid		
	Arixtra 1.5 mg/0.3 for injection	ml - Solution	7 pre-filled syri	nges E	U/1/02/206/006				Valid		
	Arixtra 1.5 mg/0.3 for injection	ml - Solution	2 pre-filled syri	nges E	U/1/02/206/005				Valid		
	Arixtra 1.5 mg/0.3 for injection	ml - Solution	20 pre-filled sy	ringes E	U/1/02/206/008				Valid		

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 the selected products not needed in this application. The proceed as previously.

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

0	Completed 🥏 Product Selection										Variation Form Human / .	Application for varia 2/586 🕁 Last Sa	tion to a marketing authorisati ved : 09/09/2022 13:12:08 i
8	Product Selection	Products c	oncerned by this a	pplication () Show 10 rows F	lefresh <i>C</i>					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 Pending	Showing 1 to	Advantan 0,1% - Creme 1 of 1 entries	Cream		Republic of Austria	UAT ORG (ORG- 200036101) LOC	1- 19575UAT		UAT600010687758	600010687758		0/0
$\mathbf{\vec{o}}$	Proposed Changes Pending	Save	'alidate Cancel	Export									

Figure 18 - Save and Validate Buttons



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

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

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

Ô	Completed © Product Selection										Variation Form Human /	Application for variat 2/586 ⊥ Last Sav	ion to a marketing authorisation ed : 09/09/2022 13:12:08 PM
Ø	Product Selection	Products (Co	concerned by this a	pplication ^① Show 10 rows F	tefresh 💋					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 Pending	∽ Showing 1 to	Advantan 0,1% - Creme o 1 of 1 entries	Cream		Republic of Austria	UAT ORG (ORG- 200036101) LOC	1- 19575UAT		UAT600010687758	600010687758		0/0
$\overline{\mathfrak{O}}$	Proposed Changes Pending	Save \	Validate Cancel	Export									



2.2.6. How to delete a product from an Application Form

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

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

0	Product Selection	Produc	ts conce	rned by this applica	tion								
	Pending 📓	Column	ı visibility	➤ Show 10 rows	Refresh 💋			As	sociate MRP N	. Sea	rch		Q + Add Produ
ぷ	Type(s) of Change(s) Pending	F	ull Iame	Authorised Dose Form	Active Substance	Authorisation Country	MA Holder	MA Nr.	MRP / CP Nr.	PMS ID	MP ID	MRP Variation Nr.	Nr. of Selected Packages
	Procedural Information Pending X	Showing	0 to 0 of	0 entries		N	o data availab	le in table					



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.

	Pending 📓 Variation Form Human / Application for variation to a marketing authoritation Product Selection> View / Select Product											
Ø		Coli	umn visibility 🗸 🤉 Ref	resh 🥑 View Availat	le Products							iearch My Products Q
以			↑ Full Name	Authorised Dose Form	Active substance(s)	Authorisation Country	MA Holder	MA Nr.	MRP/CP Nr.	PMS ID	MP ID	RPI
		2	Advantan 0,1% - Creme	Cream		Republic of Austria	UAT ORG (ORG-200036101) LOC	1- 19575UAT		UAT600010687758	600010687758	PRD/0000541100
		V	Advantan Milch 0,1% Emulsion zur Anwendung auf der Haut	Cutaneous emulsion		Republic of Austria	UAT ORG (ORG-200036101) LOC	1- 22211UAT	AT/H/0102/001UAT	UAT600010575194	600010575194	PRD/0000541057
\odot	Show	ving 1 to ve C	2 of 2 entries Cancel									

Figure 21 - View Available Products

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

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

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

2.3. Type(s) of change(s)

2.3.1. How to add a variation scope in an Application

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

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

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



- **1.** Access an existing or create a new Application Form. See sections 2.1.1, 2.1.2and 2.1.3 for further details
- 2. In the Type(s) of Change(s) page, click on Add Scope

以	Pending 🚡 Type(s) of Chang	e(s)			
0	Product Selection	Variations included for this application $^{(1)}$. Refresh $ {oldsymbol {\cal G}}$			Smooth Add Scope
	Turne(a) of	† Scope	Selected	Description	
	Change(s)			No data available in table	
	Pending 🔀				
	Procedural Information	Save Validate Cancel Export			



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

	Produg ∑ → Type(s) of Change(s)> Add/Edit Scope	
6	Selected Scope	
0	¢	
Ē	Save Cancel	

- Figure 23 Select Scope
- 4. In the 'Select Scope' window you will be presented a list of scopes with multiple pages to navigate to. The easiest and quickest way to select the scope is by typing the scope in the search field. The more you type, the further the list will be filtered making it easier to select the correct scope (the list is not auto filtered, you will need to click enter or the magnifying glass to filter further). Please note that the search is not case sensitive, i.e. you do not need to use capital letters. Please note use of roman numbers where relevant (for example to search for C.I.6, you will need to type c.i.6, not c.1.6). If you wish to look 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.

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\sim	Selected Scope		
\sim	Select Scope		To search on partial text, use the asterisk (*) wildcard character.
~>			c.i Q
	Choose one record and click Se	elect to continue	
	~	Name 🕆	
		C.1.1.a The medicinal product is covered by the defined scope of the procedure	
		C.1.1.b The medicinal product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure and no new additional data is required to be submit	ted 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 MAH	
\rightarrow		C.1.10 Change in the frequency and/or date of submission of periodic safety update reports (PSUR) for human medicinal products	
9		C.1.11.a Implementation of wording agreed by the competent authority	
_		C.1.1.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MMH where significant assessment by the competent authority is req	uired*
		C.I.I.1.2 Change in due date for category 1, 2 or 3 studies in the RMP and/or Annex II	
		C.1.11.2 Other obligations and conditions (e.g. acceed wording + ORD template)	
\odot	< 1 2 3 4	5 >	
		ſ	Select Cancel Remove value



Select Scope	a	×
		*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.5.a The activities for which the manufacturer/importer is responsible include batch release	
	A.5.b The activities for which the manufacturer/importer is responsible do not include batch release	
	A.6 Change ATC Code / ATC Vet Code	
	A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch rial, reagent or excipient (when mentioned in the dossier)*	ontrol takes place, or supplier of a starting mate
	B.I.a.1.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place	
	B.I.a.1.; Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological active splace	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. Currently it is not possible to clone/copy the selected scopes, however, a change request has been raised to be able to easily add/clone the same scopes multiple times.
- 6. 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 \bigcirc again to return to the scope selection screen



\mathcal{O}_{\Box}	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 new	v therapeutic indication or modification of an approved one	×	۹	
Select Procedure Type				_
			٩	Launch lookup modal
Identifier	Select procedure type from the			
	list			

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 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 Proced		×	
		Search	۹
Choose one record and click S	elect 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

9	
EUROPEAN MEDICINES	AGENCY HEALTH

Selected Scope *		
B.I.b.2.a Minor changes to an approved test procedure X		
Select Procedure Type *	Implementation Date *	
Variation Type IA × Q	DD/MM/YYYY	=
Identifier •		
B.I.b.2.a - Variation Type IA - 1		
Implementation Date Note		
Select Conditions		
□ Conditions ↑	Note (i)	
Appropriate validation studies have been performed in accordance with the relevant guidelines and show that the updat ed 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).	۲	
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		
□ Documentations ↑	Note ①	
Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for vet rnary products, as appropriate), including a description of the analytical methodology, a summary of validation data, revise d 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_{IN} it is mandatory to provide a date or note.

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

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

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

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



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

Ô	Product Selection	Variations included f	or this application $^{}$					Search	Add Scope
20	Type(s) of	↑ Se	cope		Selected	Description			
23	Changé(s) Pending	B	I.b.2.a Minor changes to an approved test procedure		1	B.I.b.2.a - QUALIT\ Change in test proc material/reagent/in substance - Minor o	/ CHANGES - ACTIVE SUBSTANCE - Control redure for active substance or starting termediate used in the manufacturing proc changes to an approved test procedure	of active substance - ess of the active	•
Ē	Procedural Information		1dentifier	Procedure Type		Implementation Date	Implementation Date Note	Article 5	
4-1	Pending 🔀	~	B.I.b.2.a - Variation Type IB - 1	Variation Type IB					
$\mathbf{\vec{o}}$	Proposed Changes	1 entries							
		Save Validate	Cancel Export						

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. Repeat the step by clicking 'Add scope' button. You can do this as many times as needed. Please note that it is not possible to copy/clone scope/procedure type combinations in this version of the form.
- **12.** Please note that if the same scope is added multiple times, these are differentiated by using a sequential number for each scope. This will help you to identify the scopes when you are linking the scopes and the packaged medicinal products in Present and Proposed section.

Variations inc	cluded for this application $^{(1)}$					
Refre	esh 💋				Search	Add Scope
	[↑] Scope		Selected	Description		
Ð	C.I.6.a Addition of a new therapeutic indication or m	odification of an approved one	2	C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILANC NARY MEDICINAL PRODUCTS - Change(s) to thera new therapeutic indication or modification of an ap	E CHANGES - HUMAN AND VETE peutic indication(s) - Addition o pproved one	ERI 💿
	1 Identifier	Procedure Type	Implementation Dat	e 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				٢
2 entries Showing 1 to 1 Save Val	t of 1 entries 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. How to delete a scope in an application

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



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

8	Product Selection	Variations included for this application $^{\bigcirc}$. Refresh $~~{\cal G}$		Search	Add Scope
Х,	Type(s) of Change(s) Pending	↑ Scope ∨ B.I.b.2.a Minor changes to an approved test procedure	Selected	Description B.I.b.2.a - QUALTY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure	O Delete
	Procedural Information Pending X	Sive Valdate 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.

Variations include	ed for this application $^{(i)}$					
Refresh	<i>c</i>				Search	Add Scope
	[↑] Scope		Selected	Description		
	C.I.6.a Addition of a new therapeutic indication or mo	dification of an approved one	2	C.I.6.a - SAFETY, EFFICACY, PHARMACOVIGILJ NARY MEDICINAL PRODUCTS - Change(s) to ti new therapeutic indication or modification of a	NCE CHANGES - HUM herapeutic indication(s) n approved one	AN AND VETERI O
	[↑] 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 Im Delete

Figure 33 - 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).

<i>0</i> 6	Product Selection	Procedural Information	>
<u>ک</u> ې	Type(s) of Change(s)	Name and Address of MA Holder (Applicant)	>
ē	Pending ¥ Procedural	Contact Person	>
L=	Information Pending	Save Validet Cancel Export	

Figure 34 - 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.

Procedural Information			^
Domain Human use	Type of Authorisation	Variation Procedure Number	+ Add
Type of Application Single Regulatory Activity	Name ↑ Centralised Procedure	Procedure Number ↑	
Worksharing ()		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)		
Variation Type II	□ Name		
	Indication Paediatric requirements		
	Safety Quality		
	Annual variation for human influenza vacines		
	Variation to changes related to the active substance of a human coronavirus vaccine		
	Other		
	_		

Figure 35 - Sub-section: Procedural Information

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

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

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

- Type of Application; This field is auto calculated based on the Procedure Type and number of scopes selected. Please note that the terms 'Single variation' and 'Grouping of variations' as known in the pdf are slightly different in the web user interface (single regulatory activity and Grouped regulatory activity), however, the terms from the NTA form are still used in the pdf export.
- Work-sharing; this field is auto calculated and is ticked by the system when more than one 'CAP Authorisation Products' i.e. products with different H/C/ number have been selected. Please note that the product selection is on 'Medicinal Product' level i.e. if the product selected has for example more than 1 pharmaceutical forms, and your change impacts all 'medicinal products' you should select them all, but this does not mean that the work-sharing tick box will be ticked.
- *IG/Super grouping; If more than one CAP has been selected and in addition to one or more Type IA and/or Type IA_{IN} scopes have been selected.*

 Procedure Type; this field will display the name(s) procedure type(s) selected in the Type(s) of Change(s) section (For example Variation Type II).

EUROPEAN MEDICINES AGENCY

• 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	Va	ariation Procedure Number	+ Add
ity	Name 🕆	F	Procedure Number ↑	
Variation P	rocedure Number ×		There are no records to display. Variation Procedure Numbers Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential Mutual Recognition Procedure Number according to Chapter 1 of the 'Best Practice Guides for the submission and processing of variations in the Mutual Recognition Procedure' (http://www.hma.eu).	
	Annual variation for human influenza vaccines		Vertified y Medicatal Products, Variation number to be issued by the Reference Member State before submission of the application according to the corresponding VMRFG Best Practice Guide (http://www.hma.eu). Centralised Procedure: The sequential EMA	
	Medical devices		procedure number (not the MAH's internal number) should be provided here, when known to the Marketing Authorization	
icant)			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 36 - 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 () European Medicines Agency	
Org ID ORG-100013412 Address Domenico Scarlastilaan 6 Amsterdam 1083 HS Netherlands	LOC ID LOC-100020264 Customer Account Number Modified On 12/09/2022 19:09
Phone Number Provide a telephone number	Email

Figure 37 - 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.

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

1. Click the **+** Add button

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

Figure 38 - 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	Surrame	
Email	Phone	
Title	Provide a telephone number Member State	
	×	
Company	٩	
Save		

Figure 39 - Create Application Contact

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			×
				*laitos Q
Choose o	one record and click Select to continue			
~	Organisation Name 🕇	Full address	Organisation Id	Organisation Location
	Terveyden Ja Hyvinvoinnin Laitos	Mannerheimintie 166 00300 Helsinki Helsinki-Uusimaa Finland	ORG-100019555	LOC-100039037
	Terveyden Ja Hyvinvoinnin Laitos	PI 30 00271 Helsinki Finland	ORG-100019555	LOC-100039039
				Select Cancel Remove value

Figure 40 - 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.



ⓓ	Pending 🚡 Proposed Changes		Ð
<i>0</i>	Product Selection	Precise Scope and Background for Change	>
ズ	Type(s) of Change(s)	Present and Proposed Changes	>
	Procedural	Other Applications	>
	Pending	Save Validate Cancel Export	
\odot	Proposed Changes Pending 2		



2.5.1. Precise Scope and Background for Change

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

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

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

recise scope and background for change	Background for Change		
Freise Scope for Linangen	Specify the precise present and proposed working or specification, including decisier section number()) at the lowest possible level. Click here to and the guidance Guidance for applicants for the preparation of the precise scope section of the variation application form		
Brouge Barton			
of Foot - Size - D / LL /	2 A		
		: Ξ Ξ 40 10 14 X w mm b1 14 X (2) m • 11	
Sackground for Change			
Ender test.			
Sackground for Change			
Enter test.			
Sackground for Change	2- ∆- ≡ ≔ -= = =	(単単ののスメーモス N ク C δ F Ω	

Figure 42 - 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.

Completed	Precise Scope and Background for Change ${\rm \textcircled{O}}$	>
Type(s) of Change(s) Not Completed X	Present and Proposed Changes	^
Procedural	Please add a Present and Proposed change for each Scope and Medicinal Product combination. A product area will be recommended based or selection. In addition to free text / Organisation changes, please check if structured product data needs to be updated.	n your scope
Pending Z	Proposed Change 🗸 Search Q	Add Present/Proposed
Proposed Changes Pending	□ Product MA Number(s) ↑ Scope(s) Recommended Change(s) Proposed C □ Text / Org. C	hange(s)
Finalisation	Other Applications ①	>
	Save Validate Cancel Export	
	Figure 43 - Proposed Changes	

2.5.2.1. Present and Proposed Text Changes

<i>ж</i>	Type(s) of Change(s)		Present and Proposed Changes		^
Ē	Procedural Information		Please add a Present and Proposed change for each Scope and Medicinal Product check if structured product data needs to be updated.	ombination. A product area will be recommended based on your scope selection. In a Proposed Change	uddition to free text / Organisation changes, please Q Add Present/Proposed
õ	Proposed Changes		□ Product MA Number(s) ↑ Scope(s)	Recommended Change(s)	Proposed Change(s)
\otimes	Pending		There are no records to display.		
			Other Applications ①		>
		٤	ave Validate Cancel Export		



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



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

esent and Propos	ed Value(s)	Selected Scope(s)	Selected Medicina	al Product(s)								
Present *							Proposed *					
Enter text							Enter text					
- ST Pont	• Size • B	1 <u>U</u> <u>2</u> + <u>1</u>	7. = =	** ** == = =	≣ es où x, i		Font	· Size · B	<i>I</i> <u>U</u> <u>Z</u> • <u>A</u>	- = = -= -1	- n <u>-</u>	i ≪ ≪ 1
Organisation De	ails											
Organisation Det 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)	Parent Organis ation ID (Prese nt Organisatio n)	Modified On (Pr esent Organisat ion)	Organisation N ame (Proposed Organisation)	Organisation Lo cation (Propose d Organisation)	Organisation Id (Proposed Orga nisation)	Full address (Pr oposed Organis ation)	Parent Organis ation ID (Propo sed Organisatio n)	Modified On oposed Orga ation)
Organisation Det Organisation N ot Selectable ↑ No	Organisation N ame (Present O rganisation) European Medicin es Agency	Organisation Lo cation (Present Organisation) LOC-100010800	Organisation Id (Present Organi sation) ORG-100006175	Full address (Pr esent Organisat ion) 30 Churchill Place London E14 5EU United Kingdom	Parent Organis ation ID (Prese nt Organisatio n) [INACTIVE] Eur opean Medicines Agency	Modified On (Pr esent Organisat ion) 17/07/2022 22:0 7	Organisation N ame (Proposed Organisation) European Medicin es Agency	Organisation Lo cation (Propose d Organisation) LOC-100018793	Organisation Id (Proposed Orga nisation) ORG-100013412	Full address (Pr oposed Organis ation) Orlyplein 24 104 3 DP Amsterdam Netherlands	Parent Organis ation ID (Propo sed Organisatio n) European Medicin es Agency	Modified On oposed Orga ation) 12/09/2022 1 9

Figure 45 - 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).



resent *	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.
Charge i reales lo une opoare or bis and unal charge i reales to une opoare or bits and unal charge i reales to the opoare or bis and that	Change - Heads to une dyoards of this and use, to be or text and marges. Change - Heads to use you we or tims and use. Change - Heads to the update of this and use. Change - Heads to the update of this and that.
	Next advantation Next Next Next Next Next Next Next Next
	hari
	Parate Sala
	Appropriate Description Description <thdescription< th=""> <thdescription< th=""></thdescription<></thdescription<>
	No. Del militario Statistica Statistica<
	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 relates to the update of this and that. Change 1 relates to the update of and that.
	•

Figure 46 - 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 **+** Add button to select the Present and Proposed organisations without saving.

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

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

Present and Proposed Value(s)	Selected Scope(s) Selected Medicinal Product(s)		
Present * Change 1 relates to the update of Change 1 relates to the update of t that.	f this and that. his and that. Change 1 relates to the update of this and that. Change 1 relates to the update of this and	Î	Proposed * Change 1 relates to the update of this and that. Change 1 relates to the update of this and that. relates to the update of this and that. Prevent Charge + Prevent and Frequent Value()

Figure 47 - 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 M	adicinal Product(s)		
Colum	n visibility 🗸			Filter
	Identifier	1 Scope	Recommended Change(s)	Description
•	8.II.b.1.e - Variation Type IB - 1	B.ILb.Le Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products	Text / Org. Changes	B.II.b.1.e - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except bach-release, bach control, pirmary and secondary packaging, for nonstarile 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 - Reglacement 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
0	B.II.g.1.a - Variation Type II - 1	B.II.g.1.a One or more unit operations in the manufacturing process of the finished product including the resulting in- process controls and/or test procedures	Text / Org. Changes	B.II.g.1.a - QUALITY CHANGES - FINISHED PRODUCT - Design Space and post approval change management protocol - Introduction of a new design apace or extension of an approved design space for the finished product, concerning - One or more unit operations in the manufacturing process of the finished product including the resulting in-process controls and/or test procedures

Figure 48 - 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.

9
EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

Present and Proposed Value(s) Selected Scope(s)	Selected Medicinal Product(s)			
Column visibility 🐱			Filter	٩
T Product Name	MRP / CP Number	MA Number	Authorisation Country	PMS Id
			European Union	
			European Union	_
Showing 1 to 2 of 2 entries 1 row selected				
Selected Packaged Medicinal Product(s)				
Column visibility 🐱			Filter	٩
MA Number	MRP / CP Number	PMS ID	Pack Size	Authorisation Status
				Valid
Save Close				

Figure 49 - 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 for product data needs to be updated.	each Scope and Medicinal Product combination. A product a	rea will be recommended based on your scope selection. I Proposed Change	In addition to free text / Organisation chan	ges, please check if structured Q Add Present/Proposed
□ Product MA Number(s) ↑	Scope(s)	Recommended Change(s)	Proposed Cha	nge(s)
	B.II.b.2.a - Variation Type IA - 1,B.II.b.2. A - 2	a - Variation Type I Medical Device		

Figure 50 - 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

$\mathbf{\vec{o}}$	Not Com Propo	npleted 🙁 Dised Changes >	Present and Pr	oposed Value	(5)								==		
Ô		Present and Propose	ed Value(s) Se	lected Scope(s)	Selected Medicinal	Product(s)									
ぷ		Present *							Proposed *						
		Enter text							Enter text						
õ															
Ø		Font Organisation Deta	- Size - B	Ι <u></u>	= = -= +=	" ≣ ≣ ≣	ବତେ୍୪, ⊑		I Font	- Size - B	Ι <u>⊔</u> <u></u> <i>ℓ</i> - <u></u> Δ-	= =	" = = =	ବତ୍ୟ ଅ	
\otimes												Do	this step	first 📑	Add
		Organisation No t Selectable ↑	Organisation Na me (Present Or ganisation)	Organisation Lo cation (Present Organisation)	Organisation Id (Present Organi sation)	Full address (Pr esent Organisati on)	Parent Organisa tion ID (Present Organisation)	Modified On (Pr esent Organisati on)	Organisation Na me (Proposed O rganisation)	Organisation Lo cation (Propose d Organisation)	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	0
		In case no OMS s	election is done, I dec	clare this change doe	is not affect organisa	tions unless the orga	nisation is being dele	ited							
		Save Close													

Figure 51 - Present and Proposed Value(s)

3. In the Proposed changes – Present and Proposed Value(s) – Add/Edit organisation subsection, click on the magnifying glass 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>8</i> 6	Organisation Not Selectable ①
以	Present Organisation *
٢	Proposed Organisation *
Ø	٩
\otimes	
	Save Close

Figure 52 - 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.

Organisation Not Selectable ①						
Sele	ct Present Organisation				×	
i≡ Al	I Active Locations +				Search	
Choose or	ne record and click Select to continue					
~	Organisation Name ↑	Full address	Organisation Id	Organisation Location	Status	
					Active	
					Active	
					24 March 19	
					Active	
					Active	
					Active	
					Active	
< 1	2 3 4 5 6 7 8 500 >					
					Select Cancel Remove value	





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

osed Cha	anges > View/Propose Changes	> Add / Edit Org
	atian Net Calantable (1)	
D Drganis	Organisation Not Selectable	
Present Or	The organisation is not selectable as 1) the organisation no longer exists, or 2) there is a change in organisation name which does not	



0	Organisation Not Selectable ①	
℃\$	Organisation Name *	City/Locality/Town/Village *
	Address Line 2	State
ं	Address Line 3	County
\otimes	Address Line 4	Country *

Figure 55 - 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{O}	Pending Proposed Changes > View/Propose Changes > Add / Edit Org	E
<i>0</i> _	☑ Organisation Not Selectable ①	
⊃\$	Organisation Name *	City/Locality/Town/Village *
Ē	Address Line 1	State
(i)	Address Line 3	County
	Address Line 4	Country *
	Proposed Organisation *	
\otimes		
	Save	

Figure 56 - 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.

posed 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 Orlyplein 24 Amsterdam 1043 DP Netherland	LOC ID LOC-100018793 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.

Present *							Proposed *					
Enter text							Enter text					
I Font	 Size - B 	I U 2-1	<u>A</u> • ≡ i≡ •≡ •	• • = = = =	≣ ବେ ୍ରୁ ୪, ା		I Font	- Size - B	I ∐ ⊉• A	• = = •= •		∎ @ % ∎
Organisation De	ails											
Urganisation De	tails											
Organisation De	Organisation N	Organisation Lo	Organisation Id	Full address (Pr	Parent Organis ation ID (Prese	Modified On (Pr	Organisation N	Organisation Lo	Organisation Id	Full address (Pr	Parent Organis ation ID (Propo	Modified On (i
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)	Parent Organis ation ID (Prese nt Organisatio n)	Modified On (Pr esent Organisat ion)	Organisation N ame (Proposed Organisation)	Organisation Lo cation (Propose d Organisation)	Organisation Id (Proposed Orga nisation)	Full address (Pr oposed Organis ation)	Parent Organis ation ID (Propo sed Organisatio n)	Modified On (I oposed Organ ation)
Organisation De Organisation N ot Selectable ↑ No	Organisation N ame (Present O rganisation) European Medicin es Agency	Organisation Lo cation (Present Organisation) LOC-100010800	Organisation Id (Present Organi sation) ORG-100006175	Full address (Pr esent Organisat ion) 30 Churchill Place London E14 SEU United Kingdom	Parent Organis ation 10 (Prese nt Organisatio n) [INACTIVE] Eur opean Medicines Agency	Modified On (Pr esent Organisat ion) 17/07/2022 22:0 7	Organisation N ame (Proposed Organisation) European Medicin es Agency	Organisation Lo cation (Propose d Organisation) LOC-100018793	Organisation Id (Proposed Orga nisation) ORG-100013412	Full address (Pr oposed Organis ation) Orlypiein 24 104 3 DP Amsterdam Netherlands	Parent Organis ation 1D (Propo sed Organisatio n) European Medicin es Agency	Modified On (l oposed Organ ation) 12/09/2022 19: 9
Urganisation De Organisation N ot Selectable ↑ No No	Organisation N ame (Present O rganisation) European Medicin es Agency For Health And Fo	Organisation Lo cation (Present Organisation) LOC-100010800 LOC-100000001	Organisation 1d (Present Organi sation) ORG-100006175 ORG-100003912	Full address (Pr esent Organisat ion) 30 Churchill Place London EL4 SEU United Kingdom Beethovenstrasse 6 8010 Graz Aust	Parent Organis ation 10 (Prese nt Organisatio n) [INACTIVE] Eur opean Medicines Agency Eor Health And Fo	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 For Health And Fo	Organisation Lo cation (Propose d Organisation) LOC-100018793 LOC-100000004	Organisation Id (Proposed Orga nisation) ORG-100013412 ORG-100003912	Full address (Pr oposed Organis ation) Orlyplein 24 104 3 DP Amsterdam Netherlands Traisengase 5 Br igittenau 1200 Vi	Parent Organis ation 1D (Propo sed Organisatio n) European Medicin es Agency Austrian Agency For Health And Fo	Modified On (to oposed Organ ation) 12/09/2022 19: 9 12/09/2022 14: 9
Urganisation De Organisation N ot Selectable ↑ No No	Organisation M ame (Present O rganisation) European Medicin es Agency For Health And Fo od Safety	Organisation Lo cation (Present Organisation) LOC-100010800 LOC-10000001	Organisation 1d (Present Organi sation) ORG-100006175 ORG-100003912	Full address (Pr esent Organisat ion) 30 Churchill Place London E14 SEU United Küngdom Beethovenstrasse 6 8010 Graz Aust ria	Parent Organis ation 10 (Prese nt Organisatio n) [INACTIVE] Eur opean Medicines 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 For Health And Fo od Safety	Organisation Lo cation (Propose d Organisation) LOC-100018793 LOC-100000004	Organisation Id (Proposed Orga nisation) ORG-100013412 ORG-100003912	Full address (Pr oposed Organis ation) Orlyplein 24 104 3 DP Amsterdam Netherlands Traisengase 5 Br igittenau 1200 Vi enna Austria	Parent Organis ation 1D (Propo sed Organisatio n) European Medicin es Agency For Health And Fo od Safety	Modified On (1 oposed Organ ation) 12/09/2022 19: 9 12/09/2022 14: 9
Urganisation De Organisation N ot Selectable ↑ No No	aris Organisation N ame (Present O rganisation) European Medicin es Agency Austrian Agency For Headth And Fo od Safety selection is done, I d	Organisation Lo cation (Present Organisation) LOC-100010800 LOC-100000001	Organisation 1d (Present Organi sation) ORG-100006175 ORG-100003912	Full address (Pr esent Organisat ion) 30 Churchill Flace London E14 Sturgdom Beethovenstrasse 6 8010 Graz Aust ria sations unless the or	Parent Organis ation ID (Prese nt Organisatio n) [INACTIVE] Eur Opean Medicines Agency Austrian Agency For Health And Fo od Safety ganisation is being d	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 For Health And Fo od Safety	Organisation Lo cation (Propose d Organisation) LOC-100018793 LOC-100000004	Organisation Id (Proposed Organisation) ORG-100013412 ORG-100003912	Full address (Pr oposed Organis ation) Orlypiein 24 104 3 DP Amsterdam Netherlands Traisengases 5 Br igittenau 1200 Vi enna Austria	Parent Organis ation 1D (Propo sed Organisatio n) European Medicin es Agency For Health And Fo od Safety	Modified On (1 oposed Organ ation) 12/09/2022 19: 9 12/09/2022 14: 9

Figure 58 - 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.

inspectation in	and (Property of		(Property Street	tud address (A mark Standard Mar)	and the local division of the local division	Reality of the life	Comparison in the local division of the loca		Constanting of	fail address (M second impairs along)	attan 10 (Arapa ur Ingenium at	Radified Inc. (1) second impacts allow)
-							and a second sec	100.00000000		Automatican IX	100-11-00-11-0 201-11-0	1
										1.000		
() h an a fr	adector's des. 1 a	intern 1993 Analoga da	en od affort jegerle	ation when the st	periodice is being a	1004						

Figure 59 - Pop-Up showing details inserted

2.5.2.4. Multiple change

2.5.2.4.1. 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.

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

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

2.5.2.5. Structured changes

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

2.5.2.6. Medical Device(s)

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

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

Cha all c	nge(s) concern(s) (for Type IB and Type II variations only, tick hanges applicable)
v	Name
	Medical devices

Figure 60 - Medical Device Box

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



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

Figure 61 - Add Present/Proposed Changes

3. Select the scope and the medicinal product/presentations

8	Present and Proposed Value(s) Selected Scope(s)	Selected Medicinal Product(s)		
ぷ	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.I.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
\bigcirc				
	Save Close			
\otimes	Showing 1 to 1 of 1 entries			

Figure 62 - 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 fo please check if structured product data needs	r each Scope and Medicinal Product combination. A p to be updated.	roduct area will be recommended based on your Proposed Change	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 63 - 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.



vice	C KF
Parent Medicinal Product	
No data available in table	
	*
	Add Device Remove Association(s) Delete Device(s)
Parent Medicinal Product	
No data available in table	
	~
	fice Parent Medicinal Product No data available in table Parent Medicinal Product No data available in table No data available in table

Figure 64 - 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.

I	1edical 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 65 - 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



Figure 66 - 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 67 - Device(s) Identification and Classification

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

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

Figure 68 - 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 69 - Upload of Documentation

11. Notified body is also now selected from OMS

S
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Notified Body (NB)			^
Notified Body Number *			
Name of the Notified Body *			
THe *	Eret Name *	Last Norma *	
Telephone	E-Mail		

Figure 70 - Notified Body

12. dsd

2.5.2.7. ATC Code change

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

 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 fo please check if structured product data needs	er each Scope and Medicinal Product combination. A s to be updated.	product area will be recommended based on your s	cope selection. In addition to free text / C Search Q)rganisation 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 Change((5)

Figure 71 - 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



posed Changes >	Present & Proposed Pharmacothe	erapeuti	🗁 KP 19/09/22 Medical device test / VAR/22/698 🛓 Last Saved :	19/09/
✓ Selected Sc	cope(s)			
Pharmacot	herapeutic Group (ATC)			
Present Values	s			
	[†] 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	Js to display.			
Save Cancel	Delete Proposed Change			

Figure 72 - ACT Code Change

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

Select ATC Code	×
FHIR Product ATC Code	
ATC Code	Launch lookup
If no ATC code has been assigned, please indicate if an application for ATC code has been made	modal
Same	

Figure 73 - 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

2.5.2.8. 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.



	7			
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				
NE 0 1 1 1 1			DOME OF 1 *	
MF Organisation *		Q	PSMF Code *	
MF Organisation *		٩	PSMF Code *	
MF Organisation *		٩		
MF Organisation ~		۵	PSMF-Lode ~	
WF Organisation *		α	PSMP Gode =	
NF-Urganisation -		Q	PSMP Gode =	
NF Urganisation -		م ا		
NF Urganisation -		م ا		
NF Urganisation -		م ا		
The Pharmacovigliance system m	aster file location has been registered in Art	Q icle 57 database		
The Pharmacovigliance system m i For Risk Management Plan, see i For Risk Management Plan, see	aster file location has been registered in Art module 1, 1.8.2.6 For the purposes of this a bilgations, whether or not it is owned by hir	cicle 57 database pplication form, a Qualified person Respo	nsible for Pharmacovigilance 'resides' in there.	the place where he/she makes his/her home, where he/she lives, can be traced, i

Figure 74 - Pharmacovigilance System Master File

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

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

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

2.5.2.9. 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 AGEN	VCY
SCIENCE MEDICINES HEA	LTH

Genetically Modified	Organisms		
Present Values			
MA Number	Product Name	Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?	If yes, does the product comply with Directiv 2001/18/EC?
		No	
Showing 1 to 1 of 1 entries			« 1 ;
Proposed Values			
es the medicinal product contain GMO	57 ×		
/es	~		
es the product comply with Directive 2	2001/18/EC?*		

Figure 75 - 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

2.5.3. Other applications

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

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

Figure 76 - Selection of EMA Procedure



2.6. Additional Information

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

以	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 ${}^{}$	>
Ĩ	Proposed Changes Completed	Type II variations - Extended data exclusivity / market protection	>
2	Additional Information	Save Validate Cancel Export	

Figure 77 - 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 Not (a) Yes Select Orphan Designation Procedure	٩

Figure 78 - 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 Remove value



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?	
O No @ Yes	
Select Orphan Designation Procedure	
EMA/0D/050/15	×Q
Orphan designation procedure status	
🕞 Pending 🐘 Orphan Designation Granted 🖯 Orphan Designation Refused 🔿 Orphan Designation Withdrawn	
Orphan designation date	
10/08/2015	
Based on the criterion of "significant benefit":	
No 🦉 Yes	
Number in the Community Register of Orphan Medicinal Products	
EU/9/15/1532	
🕼 Attach copy of the Designation Decision	

Figure 80 - 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 varia	ations - Paediatric Requirements ()			^
Applicable Paediatric Regulation Article 8 of Paediatric Regulation Carticle 8 of Paediatric Regulation This application relates to an This application relates to paediatric regulation Acide 8 Procedure Type This application relates to a prior This application relates to a no Cartinic application relates to a no Acide 8 New Indication Cartinic spotter by a supplementz Bio protected by a supplementation Dis protected by a patent which Cartinic application relates to paediate This application relates to paediate This application relates to paediate This application relates to paediate Cartinic ap	on applies to this variation application since. I ation does not apply to this application since. we indication for a paediatric use marketing i diatric studies included in a paediatric invest diatric studies submitted according to Article revious/ongoing/parallel procedure which trig ew indication for an authorised medicinal pro introduction for an authorised medicinal pro requalifies for the granting of the supplement ediatric studies submitted according to Article ediatric studies submitted according to Article	e. Juthorisation (PUMA). Igation plan. 45 or 46 of the paediatric regulation ugered Article 8 requirement. duct which: 2) No 469/2009. ary protection certificate. igation plan 45 or 46 of the paediatric regulation			+ Add
Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision	Agreed scope ↑	Agreed condition/indication
There are no records to displa	у,				
(Note: a copy of the PIP/Product Has this application been subject Has this application been subject ○ No	-Specific Waiver decision including the paedi : : to PIP compliance verification?	stric Committee (PDCO) opinion and	the Summary Report, is to be included in M	todule 1.10)	+ Add
The compliance document re	eference ↑				
There are no records to displa	у.				

Figure 81 - Type IB and Type II Variations – Paediatric Requirements

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



Select Paediatric Entitlement(s)						×
					Search	٩
~	Entitlement Number	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 8	173 >				
Se	ected records					
					Add Ca	incel

Figure 82 - Selection of Paediatric Entitlement(s)

2. Add the entitlement

Select Paediatric Entit	lement(s)				×
					106 Q
Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision	Agreed scope T	Agreed condition/indication
Selected records					
					Add Cancel

Figure 83 - Addition of Paediatric Entitlement(s)

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

Entitlement Number	Type of Paediatric entitlement	PIP n.	Name of active substance(s) for Decision	Agreed scope ↑	Agreed condition/indication	0
(Note: a copy of the PIP/Product-Spec Has this application been subject	ific Waiver decision including the paedia	atric Committee (PDCO) opinion and the	e Summary Report, is to be included in N	Module 1.10)		-

Figure 84 - Recap Table of Paediatric Entitlement(s)

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

Figure 85 - 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 86 - 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)	>
以	Type(s) of Change(s) Pending ∑	Declaration	>
	Procedural Information	Proof of payment	>
<u> </u>	Pending 🔀	Signatories	>
Ĩ	Proposed Changes Pending X	Save Validate Cancel Esport Finalise	
\otimes	Finalisation		

Figure 87 - Finalisation Process



2.7.1. Annexed documents (where appropriate)

An	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.
	Mack 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	thorisation(s) to be varied in accordance with the proposals given above. I declare that (Plea	se tick appropriate declarations)
Where applicable, national fees have been prepaid or will be particular to the pa	d in accordance with national requirements;	
□ For type IA notifications: the required documents as specified f	r the changes concerned have been submitted;	
This notification/application has been submitted simultaneously r, in case of worksharing involving the EMA, to the relevant Nation:	in RMS and all CMSs (for products within the Mutual Recognition Procedure and worksharing) I Competent Authorities and/or RMS/ CMS (as applicable) and the EMA;) or both to EMA and (Co-)Rapporteur (for products within the Centralised Procedure) o
\square * There are no other changes than those identified in this appl	cation (except for those addressed in other variations submitted in parallel);	
For worksharing or grouped variations affecting more than one	MA: the MAs concerned belong to the same MAH.	
 Where applicable, all conditions as set for the variation(s) conc 	med are fulfilled;	
Change(s) will be implemented from: *		
Next production run/next printing	Changes implementation date	Changes implementation comment
	DD/MM/VYYY	

Figure 89 - 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	ompetent authorities? ① proof of payment in Annex)					
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	٥
			made dam media nanda			





2.7.4. Signatories

Signatories			
Main Signatory		Additional signatory	
Surname *		Surname	
Status(Job Title) *		Status(Job Title)	
Date *		Date	
dd/mm/yyyy	E	dd/mm/yyyy	Ð

Figure 91 - 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 should be done using any external signature tool.

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.



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

P 18/09/22 Q	uality Grouping	VAR/22/649			▶ 18/09/2022 23:52:40 PM	
Export typically takes less	than a minute but can take	e longer to complete, depending on the	size of your Application. You'll get an email to notify y	ou when the process is	complete and ready to download.	
Export Started						
Column visibility Sho	ow 10 rows				Search	Q Refresh
Modified On	Created On	Requestor	Status Reason	EHTR PDF	Validation XMI	Export Message
19/09/2022 00-34-	19/09/2022 00:34:	Kristiina Duusaari	Active			export ressage
20 AM	20 AM					
owing 1 to 1 of 1 entries						

Figure 92 - 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	g VAR/22/649			B) TBIDAIX02X X3:22:40 MM	
xport typically takes less	s than a minute but can tak	e longer to complete, depending on the s	size of your Application. You'll get an email to notify	you when the process is	complete and ready to download.	
			Completed			
			Download 🛓			
Column visibility Sh	ow 10 rows				Search	Q F
Column visibility Sh	ow 10 rows Created On	Requestor	Status Reason	FHIR PDF	Search Validation XML	Q F

Figure 93 - 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.

		×	Attachments	þ
		Ca	E - 💪 🖺 💪 🗊	П
			Name	
			C eAF.xml	Ø
		3:06	Name: eAF.xml Modified: 18/09/2022 21:	
		_	Size: 880.61 KB	
23:01 (UTC)	Generated: 2022-09-1			
	TABLE O			
PLICAT	1. /			
	2. 1			
e IB an	4.a 1	1		
23:01 (UTC) CONTE PLICAT ODUCT PES OF ie IB ar	Generated: 2022-09-1 TABLE O 1. // 2. 3. 3. 4.a	3:06	E V C C C C C C C C C C C C C C C C C C	

Figure 95 - FHIR xml

Figure 94 - Exported Form





Figure 96 - 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 Forum

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

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

- 1. EMA Service Desk for questions on the use of the portal and for reporting faults;
- 2. EMA Account Management for access and registration requests;
- 3. <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.

4.2. *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.	
E	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	
	PLM Portal – eAF How to fill in the "Procedural Information" sectio	n
	PLM Portal – eAF How to fill in the "Additional Information" section PLM Portal – eAF How to fill in the "Finalisation" section	
	Please provide as much detail as possible (incl. step-by-step narrative and/or screenshot(s) as attachments, if/when applicable). Example: report an issue pertaining the filling of an electronic Application Form Web-user interface / Data / Access / FHIR XML / PDF export / Regulation / Other	
Indicates required		
 Indicates required Raise this request on behalf of Kristiina Puusaari 	×	Ŧ
Aaise this required Raise this request on behalf of Kristiina Puusaari	×	Ŧ
Raise this required Raise this request on behalf of Kristiina Puusaari Subject	×	Ŧ
Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description	×	Ŧ
Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description	×	Ŧ
Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description	×	Ŧ
 Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description Problem area 	×	*
Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description Problem area		*
Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description Problem area	×	Ŧ
Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description Problem area Urgency None	X	* *
Indicates required Raise this request on behalf of Kristiina Puusaari Subject Description Problem area Urgency None	×	*

Figure 97 - 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 the	re.
	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" s PLM Portal – eAF How to fill in the "Additional Information" s PLM Portal – eAF How to fill in the "Finalisation" section	ection ection
	Please provide as much detail as possible (incl. step-by-step nam and/or screenshot(s) as attachments, if/when applicable). Examp report an issue pertaining the filling of an electronic Application Web-user interface / Data / Access / FHIR XML / PDF export / Regulation / Other	rative ble: Form: /
Indicates required Raise this request on behalf of		
U Kristiina Puusaari		×
Subject		
Subject Description		
Subject Description		
Subject Description		
Subject Description Problem area		





4.3. The PLM Chatbot

...

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

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

Product Lifecycle Management Portal		♠ Home Forum SPOR ▾ IAM Sign in
Welcome to PLM Por A secure online portal for managing electronic Ap Information (eP1) and authorised product data (Pi collaboration with the European Medicines Regula Sign In > Quick links	tal plication Forms, electronic Product MS) in the European Union, in tory 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. Please choose one of the following topics: PLM Portal - eAF Post-authorisation
Public Register & 0 List 0	Guidance & O Support	le Xust now Type your message
	Figure 99 - PLM Chatbot	·