



28 November 2022

PLM Portal eAF - Release Notes

EMA is pleased to announce the web-based Human Variations electronic application form (eAF) for Centrally Authorised Products (CAPs) has gone live on **4th November 2022**, on the new [Product Lifecycle Management \(PLM\) Portal](#). This is a big, first, milestone in the ongoing journey to improve the eAF and related processes. EMA has been collaborating with the UNICOM consortium to develop the human variation form and other new web-forms.

Following the release, users of the Human Variations eAF should expect continual work on improvements in the form of regular releases. These will be a mix of bug fixes, scheduled improvements, improvements based on user acceptance testing (UAT) feedback or that may be identified by users after the release and new features, such as additional structured data fields.

Reminder: the use of the new web-based form is optional. This release will not trigger the transition period towards mandatory use. The formal **transition period** will start when nationally authorised products (NAPs) and features supporting use cases covered by the interactive pdf eAF will be added to the form. The current interactive PDF eAF will remain available until the end of the transition period.

The new PLM Portal will in due course host all eAFs. In the future it will also host the data input user interface for [product management service \(PMS\) data](#) and the interface to provide data for [electronic Product Information \(ePI\)](#). The PLM Portal will develop over time to inform and support you in the use of these services. One new feature launched on the PLM portal is a **chatbot** through which you can ask questions about the web-forms and get quick answers.

This document lists and briefly describes the new features and fixed issues included in the release of the PLM Portal.

The most recent release appears first.



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About this Document

This document lists and briefly describes the new features and fixed issues included in each release of the PLM Portal.

The most recent release appears first.

The known issues are categorised per component or business process of the system so that users can easily identify which issues are relevant for them. The components currently used are:

Component	Short Description
PLM Portal	This component relates to the website, the UI (user interface),
Human Variations eAF	The business process where MAH's create and edit their variation eAF (electronic application form) on the PLM Portal.
PDF	The PDF that is available for download after the completion of an application
FHIR XML	The FHIR xml file attached to exported PDF

For additional information on the PLM portal see this:

- User guidance recording on the PLM Portal:
- User guidance documentation on the the PLM Portal:
- If you encounter any issue that is not addressed by the above, visit the EMA Service Desk portal: <https://support.ema.europa.eu/esc>
- For more general information, please visit: <https://esubmission.ema.europa.eu/cessp/cessp.htm>

Version: 1.0.1.2 (Release date 28/11/2022)

Version Goal: Go-Live PLM Portal

Date: 28/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.1.2	This release note is for the BUGFIX version 1.0.1.2 release go-live 28/11/2022
Implementation of the human readable pdf export	PDF Version 2.0.2	This release note is for the BUGFIX version 2.0.2 release go-live 28/11/2022

Issues fixed in this version

ID	Description	Comments
27878 – FHIR XML	Dissonance between the packaged products selected on the DADI form and the ones in the FHIR Message (XML)	Although the selected Medicinal Products were taken into account in the PDF, the packaged products weren't listed correctly. This fix is visible in the PDF version 2.0.2. There is no change to FHIR version.
23407 – web eAF	Text is cut into two halves and displaying below	In the procedural information section the text 'annual variation for human influenza vaccines' was cut in the middle of the word influenza.

Known Issues

ID	Component	Short description
Known limitation	PLM Portal	Copy application feature not available yet
Known limitation	Human Variations eAF	Cannot select 'includes line extension' when single scope added
Known limitation	Human Variations eAF	It is not possible to change the 'Friendly name'
Known limitation	Human Variations eAF	Form cannot be used for variations that add new presentation
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
Known limitation	Human	Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional

	Variations eAF	Information section
Known limitation	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)
Known limitation	FHIR xml	Commercially Confidential Data not related to the application content/variation present in the FHIR XML
Known limitation	Human Variations eAF	The system creates an empty row in summary of Present and Proposed when 'save' is pressed after filling in certain sections. The empty row should be edited to contain the changes or deleted
Known limitation	Human Variations eAF	Other Applications – Select EMA Procedure has no related procedures available for selection. Workaround: use the +Add to manually add other ongoing applications
Known limitation	Human Variations eAF	Present and Proposed section: ASMF number and DUNS number fields missing from the Web UI. If these need to be provided, please use Precise Scope section or the interactive pdf eAF.
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
23910	Human Variations eAF	eAF allows only two signatories
23910	Human Variations eAF	Inconsistent button behavior by viewing 'selected packaged medicinal product(s)'
24816	Human Variations eAF	Validation error in product selection is incorrectly showing up if 'Validation' is pressed immediately after Saving
16209	Human Variations eAF	Symbol "?" is displaying in font style drop down
22733	Human Variations eAF	Error for product and scope selection, package check box is disabled
22845	PLM Portal	Deletion of Application Form is not working
23545	PLM Portal	Performance issues
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily

23851	Human Variations eAF	Search on present-proposed disappearing
23896	Human Variations eAF	Error after wrong date format for Implementation date
23912	Human Variations eAF	Menu handling checkbox - Additional information does not disappear where it should have
23913	Human Variations eAF	Precise Scope & Background Info Pop-Up
23915	Human Variations eAF	Organisation information - parent organisation label does not match
23923	Human Variations eAF	Drop down list member state country doesn't open - intermittent
23931	Human Variations eAF	Double-clicking Save button for Change(s) Scope creates duplicates
23961	PLM Portal	Drop-down invisible in Application Forms overview
23963	Human Variations eAF	Changes Implementation Date issue
23963	Human Variations eAF	Finalisation: Statement in Annexed document and Declaration Section in random order in DADI
23965	Human Variations eAF	Conditions and documentation in DADI are not in the same order as in the variation classification guideline
23966	Human Variations eAF	Not possible to paste an image to the Present and Proposed fields in the Present and Proposed Value(s) tab
23967	Human Variations eAF	Finalisation section - Proof of payment - able to select either Yes or NO
23968	Human Variations eAF	Hyphenations are incorrect in tab type of changes, in the view scope and description and in the view conditions and documentation section
23969	Human Variations eAF	Cannot select more than one organisation in Proposed Organisation field
23971	Human Variations eAF	Proposal for Organisation Details – Split Text
23974	Human Variations eAF	Suggestion - Scope section - Information is not displayed in a user-friendly manner.
24006	PLM Portal	Refresh button producing error on Application list view

24810	PLM Portal	Email template populate incorrectly after sending "Notify" email to co-author
24905	PDF	Country name shown is long version in PDF
24907	Human Variations eAF	Select all checkbox does not "Select All" in "Proposed Changes" section
25269	Human Variations eAF	Product select screen shows 0/0 product presentation
25301	Human Variations eAF	Precise scope and background for information section not saved
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.1 (Release date 14/11/2022)

Version Goal: Go-Live PLM Portal

Date: Variation eAF 14/11/2022, PDF 17/11/2022, FHIR XML 16/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.1.1	This release note is for the BUGFIX version 1.0.1.1 release go-live 14/11/2022
Implementation of the human readable pdf export	PDF Version 2.0.1	This release note is for the BUGFIX version 2.0.1 release go-live 17/11/2022
Implementation of the FHIR	FHIR XML	This release note is for the BUGFIX version 1.0.2.0 release go-live

xml	1.0.2.0	16/11/2022
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Issues fixed in this version

ID	Description	Comments
24816 – web eAF	RPI cannot be blank validation message is displaying always when CAP product is selected	<p>Remaining known issue: Validation error in product selection is incorrectly showing up if 'Validation' is pressed immediately after Saving.</p> <p>This issue has been partly fixed; the incorrect list was linked to the products resulting RPI validation issue for every product. This part of the issue has been addressed.</p>
24731 – web eAF	The Proposed Package Item Content is not linked to Application Form	The Proposed Package Item Content created when Present Package Item Content doesn't exist and has no link to Application Form and Application Form Type. Hence these records are not available for FHIR XML creation and doesn't reach PDF.
24728 – web eAF	Update Chatbot look and feel	
24649 – web eAF	Additional information section is displaying as completed without validate/export	Additional information section was automatically changed to 'completed' status when it was not filled in/validated by the user. After the bugfix the additional information section remains in 'not completed' state until the user manually validates the section
24819 – web eAF	PDF export is taking long time and loading is displaying for long time	This issue was affecting forms where there were more than 10 medicinal products selected.
24991 – web eAF	Medical device is displaying proposed changes without click on save	Medical device section was displayed even when the user clicked 'cancel' button and no changes were made and no save button was pressed.
24703 – web eAF	Incorrect date sorting for Export window	The list of pdf exports was displayed in random order.
24805 – web eAF	Prompt message on 'Delete device'	Issue relating to 'Delete device' button has been fixed.
24924 – web eAF	Validation button is not working in all sections	Validate button was not working correctly in all sections.
24990 – web	Validation error message is	Scrambled validation error message is not be shown

eAF	displayed in proposed changes section after combining scopes and packaged medicinal products	when scope and product combinations are updated.
26295 – FHIR XML	The HTML Change Provenance (unstructured provenance) doesn't contain the HTML changes when the proposed value and the present value are the same	This issue resulted a missing present and proposed section in the FHIR XML and in the pdf export when same value was presented in both 'present' and 'proposed' fields e.g. if user had added 'see details on separate annex' in both fields, the present and proposed sections were not available in the xml and were hidden in the pdf.
26247 – FHIR XML	Impossible to use the same image twice in the text areas in a form	
22013 - pdf	Updated text for the 'no address change' in the declaration in present and proposed section	The text has been aligned to correspond with the updated text as per pdf eAF release on 14 th October 2022. The text now reads 'I declare this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder. This update was done to ensure the correct use of the section – for any change that concerns an organisation e.g. change of a manufacturing site, the site must be selected from OMS. For further details on the use of this section please see: European Medicines Agency practical guidance on the application form for centralised type IA and IB variations page 13
24738 – pdf	<ul style="list-style-type: none"> Removed APPENDIX section Structured changes are shown in section 3 Text in HTML fields is same size as all the PDF 	The appendix part of pdf was deleted as non-relevant. The changes are now reflected in the present and proposed section where relevant e.g. ATC code. The text size in Precise scope and Background sections and the Present and Proposed fields is now same size as in all other fields in the pdf making the form content easier to read.

Known Issues

ID	Component	Short description
27565	Human Variations eAF	3 new tick boxes related to personal data are missing from the Declaration section when SPC, PI or labelling is ticked in Annexed documents section. This causes a validation error at time of

		<p>finalisation of the form.</p> <p>Note: This does not result in business validation error as this is a known bug in the form.</p>
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Known limitation	Human Variations eAF	Cannot select 'includes line extension' when single scope added
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Known limitation	Human Variations eAF	Other Applications – Select EMA Procedure has no related procedures available for selection. Workaround: use the +Add to manually add other ongoing applications
Known limitation	Human Variations eAF	Present and Proposed section: ASMF number and DUNS number fields missing from the Web UI. If these need to be provided, please use Precise Scope section or the interactive pdf eAF.
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
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25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page

23910	Human Variations eAF	eAF allows only two signatories
23910	Human Variations eAF	Inconsistent button behavior by viewing 'selected packaged medicinal product(s)'
16209	Human Variations eAF	Symbol "?" is displaying in font style drop down
22733	Human Variations eAF	Error for product and scope selection, package check box is disabled
22845	PLM Portal	Deletion of Application Form is not working – Using 'delete application form' in the deactivated folder results the deactivated form being moved back to 'Drafts'
23545	PLM Portal	Performance issues
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Version: 1.0.0.0 (Release date 04/11/2022)

Version Goal: Go-Live PLM Portal

Date: 04/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the Product Lifecycle Management Portal	PLM Portal	This implementation is the first version of the portal
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.0	This implementation is the first version of the web-based form for human variations based on the NTA APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, September 2021
Implementation of the human readable pdf export	PDF Version 2.0.0	This implementation is the first version of the pdf rendition export
Implementation of the FHIR xml	FHIR XML 1.0.0	This implementation is the first version of the FHIR xml export

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