



3 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 today, **4 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: 1.0.0.0

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

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	Delay in display of packaged medicinal products in product selection.

	Variations eAF	
Known limitation	Human Variations eAF	Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional 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

Outstanding issues