20 September 2024

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.

Following a successful updated product load in April 2024, the use of the web-based eAF is now **strongly recommended** for all Centralised Procedure variation applications (where possible). Please note that small number of limitations still exists in the system, however, the use of the web-based form should start becoming the first option and the use of the interactive pdf should be only in cases where the use of the web-based form is not yet possible/feasible in the view of limitations.

The formal **transition period** will start when nationally authorised products (NAPs) and features supporting all 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.

Table of Contents

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: 1.0.1.19 (Release date 18/09/2024)

Version Goal: PLM Portal bug fix release

Date: 18/09/2024

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 1.0.1.19	This release note is for the version 1.0.1.19 release go-live 18/09/2024

Issues fixed in this version

ID	Description	Comments
193714	Performance improvements – Product selection	New search functionality in the product selection window (the table doesn't show any product initially, the user must search the products; each column can be filtered)
163771	Norway, Iceland, Lichtenstein entries filtered	Ther CAPs are showing only once in the product selection window, the entries for Norway, Iceland and Lichtenstein are not visible anymore

Coming soon/we are currently working on

ID	Component	Short description
Various	Human Variations eAF	Performance improvements
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily

Known Issues

ID	Component	Short description

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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
Known limitation	PLM Portal	22845 – Deletion of Application Form is not yet available
Intermitted known issue	Human Variations eAF	25400 - Incorrect calculation of number of selected scopes in the summary page
Known limitation	PLM Portal	23545 - Performance issues
Known limitation	Human Variations eAF	23963 - Finalisation: Statement in Annexed document and Declaration Section in random order in DADI
Known limitation	Human Variations eAF	23965 - Conditions and documentation in DADI are not in the same order as in the variation classification guideline
Known limitation	Human Variations eAF	23971 - Proposal for Organisation Details – Split Text
Product data quality/duplication of data	Human Variations eAF	Product select screen shows 0/0 product presentation – this issue is derived from product duplication error caused by the system/incorrect data entry in xEVMPD leading to data error in PMS

Version: 1.0.1.18 (Release date 06/09/2024)

Version Goal: PLM Portal bug fix release

Date: 06/09/2024

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 1.0.1.18	This release note is for the version 1.0.1.18 release go-live 06/09/2024

Issues fixed in this version

ID	Description	Comments
200733	Application form ID added to the PDF	The application form ID (for example: VAR/24/1234) is now on the exported PDF, at the bottom of the page
204228	Label "Changes implementation comment" added to the PDF	In the "Declaration of the application" section in PDF, the comment related to the implementation is now labelled with "Changes implementation comment"
200739	Additional signatory and proof of payment – location in PDF	The main and additional signatory and proof of payment sections are now separate in the PDF
192307	Clone application - Block application during cloning	Some functions of the eAF are temporarily blocked when the cloning of an application has started. Maintenance popup messages are visible on the screen while the cloning is being finalised; a maintenance popup message will appear when opening an application that was not cloned properly, guiding the users on the possible actions to be taken
201530	Bug – Proposed changes	The proposed changes text appears now for all applications in the Present/Proposed list
135095	Bug – Medical device	The update of manufacturing and notified body is now reflected correctly in the medical device section

Coming soon/we are currently working on

ID	Component	Short description
Various	Human Variations eAF	Performance improvements
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily

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Known limitation	Human Variations eAF	23971 - Proposal for Organisation Details – Split Text
Product data quality/duplication of data	Human Variations eAF	Product select screen shows 0/0 product presentation – this issue is derived from product duplication error caused by the system/incorrect data entry in xEVMPD leading to data error in PMS

Version: 1.0.1.17 (Release date 27/08/2024)

Version Goal: PLM Portal bug fix release

Date: 27/08/2024

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 1.0.1.17	This release note is for the version 1.0.1.17 release go-live 27/08/2024

Issues fixed in this version

ID	Description	Comments
183078	Performance improvements – Product selection	Performance improvements were implemented for the Product selection section: after adding a new product several functions (i.e. Add product, Export, Finalise) are **blocked** until all the processes in the background are finalised, and the user will see a popup message "We are currently executing critical maintenance tasks, including data synchronisation and computational adjustments, on your application. To ensure the highest level of data integrity, access to certain functionalities will be temporarily restricted. We appreciate your patience and understanding while these enhancements are underway." The functions will be accessible once the processes are finished.
193717 164815 193709 193727	Performance improvements	Performance improvements were implemented for the following sections of the application: - Procedural information - Left navigation menu - View eAF list - Create new eAF

134341	Bug - Validation error "The field EMA procedure number/Competent Authority is required."	In the additional details, for "Type IB and Type II variations - Paediatric Requirements", the validation error "The field EMA procedure number/Competent Authority is required." does no longer appear upon saving the page.
189849	Bug - Ordering of Products on Product Selection	The display of the products on Product selection section is again based on alphabetical order.
189854	Bug – packages	Packages are now loading faster under Product selection and Present/Proposed section
197043	Bug – View selected products	In the "View selected products", now all selected products are shown
199677	Bug – Signatory date	In the main and additional signatory, the date remains as selected by the user

Coming soon/we are currently working on

ID	Component	Short description
Various	Human Variations eAF	Performance improvements
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily

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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
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Known limitation	Human Variations eAF	23971 - Proposal for Organisation Details – Split Text
Product data quality/duplication of data	Human Variations eAF	Product select screen shows 0/0 product presentation – this issue is derived from product duplication error caused by the system/incorrect data entry in xEVMPD leading to data error in PMS

Version: 1.0.1.16 (Release date 08/08/2024)

Version Goal: PLM Portal bug fix release

Date: 08/08/2024

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 1.0.1.16	This release note is for the version 1.0.1.16 release go-live 08/08/2024

Issues fixed in this version

ID	Description	Comments
187787	Orphan products – replace column in Additional information	Display the date of the first authorisation in the Orphan Products subsection and Additional Information section replacing the existing field Authorisation status state for

ID	Component	Short description
		all the level of products (Authorisation, Medicinal and Packaged)
26203	Number of selected packages fix	The number of selected packages is now shown correctly in the product selection tab after changing the selection in the Present/Proposed section
197933	PDF Fix	"Information on harmonisation of product information for MRP/DCP/purely nationally authorised products" now is showing correctly in the Signature section

Coming soon/we are currently working on

ID	Component	Short description
Various	Human Variations eAF	Performance improvements
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily

Known Issues

ID	Component	Short description
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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
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Known limitation	Human Variations eAF	23971 - Proposal for Organisation Details – Split Text
Product data quality/duplication of data	Human Variations eAF	Product select screen shows 0/0 product presentation – this issue is derived from product duplication error caused by the system/incorrect data entry in xEVMPD leading to data error in PMS

Version: 1.0.1.15 (Release date 22/07/2024)

Version Goal: PLM Portal bug fix release

Date: 22/07/2024

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 1.0.1.15	This release note is for the version 1.0.1.15 release go-live 22/07/2024

Issues fixed in this version

ID	Description	Comments
187483	Add package improvements	The lookup in the parent medicinal product opens a new window where the medicinal products selected in the application can be filtered. When a new package is added for a specific product, that product is auto-selected for the scope that is being edited.
195791	Second signatory fix	A bug causing an empty second signatory to be shown in the exported PDF was fixed.

22513	Pending products	The filters applied to the products were changed to include pending products.
194331	Copy application fix	A bug related to the "next" button on the second page in the process of copying an application was fixed.
194960	Finalisation fix	A bug related to the finalisation of a form was fixed.
194350	Note in type of changes fix	A bug related to the notes from types of changes disappearing was fixed.
195926	Proof of payment PDF fix*	Telephone number and email related to proof of payment are now correctly mapped in the PDF
197870	Active substance PDF fix*	Active substance, if identical for several medicinal products, is no longer multiplied in the PDF

related to the PDF, added in the release notes on the 30th of July

Coming soon/we are currently working on

ID	Component	Short description
Various	Human Variations eAF	Performance improvements
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily

Known Issues

ID	Component	Short description
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
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Known limitation	Human Variations eAF	23971 - Proposal for Organisation Details – Split Text
Product data quality/duplication of data	Human Variations eAF	Product select screen shows 0/0 product presentation – this issue is derived from product duplication error caused by the system/incorrect data entry in xEVMPD leading to data error in PMS

Version: 1.0.1.14 (Release date 15/07/2024)

Version Goal: PLM Portal bug fix release

Date: 15/07/2024

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 1.0.1.14	This release note is for the version 1.0.1.14 release go-live 15/07/2024

Issues fixed in this version

ID	Description	Comments
25715	Human Variations eAF	'Add package' to enable the use for variations that add new presentation
184243	Updated validation error message for 'Change(s) Concern(s)'	The validation error message has been updated to clarify the business rule in 'Change(s) Concern(s)' field.
181541	Organisations using 'OMS' status	Organisations used in eAF are now retrieved based on OMS status. This change will also prevent accidental selection of inactive organisations as the correct OMS status is displayed with it's status).

Coming soon/we are currently working on

ID	Component	Short description
Various	Human Variations eAF	Performance improvements
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily

Known Issues

ID	Component	Short description
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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
Known limitation	PLM Portal	22845 – Deletion of Application Form is not yet available
Intermitted known issue	Human Variations eAF	25400 - Incorrect calculation of number of selected scopes in the summary page
23545	PLM Portal	Performance issues
Known limitation	Human Variations eAF	23963 - Finalisation: Statement in Annexed document and Declaration Section in random order in DADI
Known limitation	Human Variations eAF	23965 - Conditions and documentation in DADI are not in the same order as in the variation classification guideline
Known limitation	Human Variations eAF	23971 - Proposal for Organisation Details – Split Text
Product data quality/duplication of data	Human Variations eAF	Product select screen shows 0/0 product presentation – this issue is derived from product duplication error caused by the system/incorrect data entry in xEVMPD leading to data error in PMS

Version: 1.0.1.13 (Release date 13/05/2024)

Version Goal: PLM Portal bug fix release

Date: 13/05/2024

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 1.0.1.13	This release note is for the version 1.0.1.13 release go-live 13/05/2024

Issues fixed in this version

ID	Description	Comments
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
164785	Performance improvements for Applications List page	The applications list page has been performance optimised. 50 most recent forms created/edited will be shown on the page, to see other, previously created/edited forms new 'Load more' button has been added. Note: The search only searches within the first 50 entries if the 'load more' has not been clicked.
164785	Human Variations eAF	Form type (variation) auto selected to improve user experience (no need to select a single value from a list.
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
174539	eAF product deletion from Application	When product has been deleted from the system, it will also be deleted from the FHIR

Coming soon/we are currently working on

ID	Component	Short description
25715	Human Variations eAF	'Add package' to enable the use for variations that add new presentation
29121	Human Variations eAF	Improve communication – guidance and support page

ID		
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal

Known Issues

ID	Component	Short description
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
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	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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
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
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
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
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

Version: 1.0.1.13 (Release date 05/02/2024)

Version Goal: PLM Portal bug fix release

Date: 05/02/2024

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 1.0.1.13	This release note is for the version 1.0.1.13 release go-live 05/02/2024

Issues fixed in this version

ID	Description	Comments
11086	Clone application (copy application)	Applicants can now clone (copy) an existing application form to reduce administrative work. It is possible to fully clone the application or copy certain application details and change the MAH. We are aware of a rare cases where the clone is not copying all fields/sections for example for medical devices or GMO. Also, please note that it can take up to 2 minutes to create the clone. If the copy function has not worked, you will get an error message and depending on the issue, you can try again or raise a service desk ticket with details of the incident. If you experience issues, kindly write a support ticket with the variation ID.
132950	Packages are not showing up	Intermitted issue where packages are not displayed in the present and proposed section has been solved in relation to upcoming feature 'add package'.

Coming soon/we are currently working on

ID	Component	Short description
6770 (246)	Human Variations eAF	Rename application
25715	Human Variations eAF	'Add package' to enable the use for variations that add new presentation

| 29121 | Human Variations eAF | Improve communication – guidance and support page |

Known Issues

ID	Component	Short description
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
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	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour by viewing 'selected packaged medicinal product(s)'
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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

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
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
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
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

Version: 1.0.1.12 (Release date 27/11/2023)

Version Goal: PLM Portal bug fix release

Date: 27/11/2023

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 1.0.1.12	This release note is for the version 1.0.1.12 release go-live 27/11/2023

Issues fixed in this version

ID	Description	Comments
37644	Clone variation scope	Applicants can now clone an existing scope to reduce administrative work, if an application should contain the same scope multiple times. We are aware of a very rare case where the clone is not showing up right away and requires a page refresh. If you experience this issue, kindly write a support ticket with the variation ID and the version of the browser you are using.
n/a	Version number correction	The version number of the eAF was updated to 1.0.1.12

Coming soon/we are currently working on

ID	Component	Short description
11086	PLM Portal	Copy application feature not available yet
246	Human Variations eAF	It is not possible to change the 'Friendly name'
25715	Human Variations eAF	Form cannot be used for variations that add new presentation
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
29121	Human Variations eAF	Improve communication – guidance and support page

| 35130 | Human Variations eAF | Improve communication – change guidance documentation on login page from IRIS to PLM Portal |

Known Issues

ID	Component	Short description
133199	Human Variations eAF	Cloned scopes do not appear immediately, only after a page refresh
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
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
38300	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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
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
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
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

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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.11 (Release date 07/08/2023)

Version Goal: PLM Portal bug fix release

Date: 07/08/2023

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 1.0.1.11	This release note is for the BUGFIX version 1.0.1.11 release go-live 07/08/2023

Issues fixed in this version

ID	Description	Comments
101118	View coordinators on co-authors	Users can see in the "Co-authors" page of an application the coordinators with implicit access to that form

Coming soon/we are currently working on

ID	Component	Short description
11086	PLM Portal	Copy application feature not available yet
246	Human Variations eAF	It is not possible to change the 'Friendly name'
25715	Human Variations eAF	Form cannot be used for variations that add new presentation
37644	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
29121	Human Variations eAF	Improve communication – guidance and support page

ID		
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal

Known Issues

ID	Component	Short description
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
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
38300	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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
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
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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
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
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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.10 (Release date 26/07/2023)

Version Goal: PLM Portal bug fix release

Date: 26/07/2023

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 1.0.1.10	This release note is for the BUGFIX version 1.0.1.10 release go-live 26/07/2023

Issues fixed in this version

ID	Description	Comments
109812	Finalising of the form not possible for certain roles	The regression bug was fixed, and the finalisation of the forms is possible also for Applicant Manager/Coordinator/Admin/Competent Authority roles
22039	Impossible to identify from the product selection window which MA number is being selected for some products	The MA number is visible in the product selection window
23531	MRP/CP Number column empty in Selected Packaged Medicinal Product(s) view	Users are able to see the MRP/CP number on packages, based on their parent medicinal product.
104314	MAH phone number and email missing in the exported pdf	The regression bug was fixed, and the MAH phone number and email are visible in the exported PDF

Coming soon/we are currently working on

ID	Component	Short description
11086	PLM Portal	Copy application feature not available yet

246	Human Variations eAF	It is not possible to change the 'Friendly name'
25715	Human Variations eAF	Form cannot be used for variations that add new presentation
37644	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
29121	Human Variations eAF	Improve communication – guidance and support page
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal

Known Issues

ID	Component	Short description
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
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
38300	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page

15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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
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
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
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
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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.9 (Release date 13/06/2023)

Version Goal: PLM Portal bug fix release

Date: 13/06/2023

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 1.0.1.9	This release note is for the BUGFIX version 1.0.1.9 release go-live 13/06/2023

Issues fixed in this version

ID	Description	Comments
16208	Select All button must select all the available records in Available Products table and Packaged Products table	Also products that are not displayed on the page (in case of pagination) are selected when select all button is used. **NOTE:** only packages that have been loaded already will be selected. It is very important to check that all packages needed have been loaded and selected prior to finalising the form.
23547	Procedural information: Some mandatory fields are not mandatory in the form	The following fields are now mandatory: • MAH contact details (telephone and email address). • MAH contact person (contact details and the organisation) • Procedure number (where relevant)
23896	Error after wrong date format for Implementation date	When the implementation date format is entered incorrectly (in Type(s) of Change(s) Type IA/Type IAIN only, the correct validation message is now displayed.
25396	Packaged medicinal products are not shown when	An issue related to display of packaged medicinal products in some applications has now been fixed and all packaged medicinal products for the selected

	combining scopes and medicinal products	medicinal products should now be visible in the Proposed changes section. **NOTE:** This is a partial fix to the issue as only those product/packages that have been loaded by the system are **visible**. There is a **delay** in loading the packages in Present and Proposed table. The delay issue will be addressed in a future release.
76861	Select All in combination with pagination will delete the previous selection	An issue related to applications containing more than 50 packaged medicinal products has been fixed. It is now possible to select all packages for all selected medicinal products **NOTE:** There is a known issue affecting this section and only approx. 200 packages can be selected at one time.
77891	Update the Validation Status of Procedural Information Section	Any field validation change should update the validation status. **NOTE:** This is a partial fix to the issue. The section level validation will remain valid (green) and will only reflect the 'not completed' status only if the 'validate button is repressed. Field level validation errors are shown correctly.
86890	Packages may not be loaded in when present/proposed is opened	The packages table on the proposed changes screen will now have a loading circle (spinner) to indicate that it is waiting on backend processes to finish creating the relevant records. Once the backend processes finish, the spinner will disappear, and the table will be loaded. There is no need to refresh the page as the table will load on its own.
93686	Friendly name validates at 100 chars but fails at 80 chars already	A technical issue (bug) detected on the background preventing finalisation of the eAF with a Friendly name exceeding 80 characters has been fixed.
94280	MAH phone number should validate without save	The validation error is no longer displayed when the 'validate' button is pressed after including the MAH phone number.
95272	Procedural Information - Reference Member State field error	Only relevant to WS procedures that do not contain any CAPs (fixed in preparation for NAPs release): • The error message on RMS now has its own line

		• There is a red border around the RMS field if no country has been selected as the RMS.

Coming soon/we are currently working on

ID	Component	Short description
11086	PLM Portal	Copy application feature not available yet
246	Human Variations eAF	It is not possible to change the 'Friendly name'
25715	Human Variations eAF	Form cannot be used for variations that add new presentation
37644	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
29121	Human Variations eAF	Improve communication – guidance and support page
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal

Known Issues

ID	Component	Short description
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
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
38300	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/has only limited procedures

		available for some products. **Workaround**: use the +Add to manually add other ongoing applications
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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
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
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
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
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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.8 (Release date 16/05/2023)

Version Goal: PLM Portal bug fix release

Date: 16/05/2023

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 1.0.1.8	This release note is for the BUGFIX version 1.0.1.8 release go-live 16/05/2023
Update of the human readable pdf export	PDF version 2.0.5.1	This release note is for the BUGFIX version 2.0.5.1 release go-live 20/02/2023
Implementation of the FHIR xml	FHIR XML 1.1.2.0	

Issues fixed in this version

ID	Description	Comments
25396	Packaged medicinal products are not shown when combining scopes and medicinal products	An issue related to display of packaged medicinal products in some applications has now been fixed and all packaged medicinal products for the selected medicinal products should now be visible in the Proposed changes section. **NOTE:** This is a partial fix to the issue as only those product/packages that have been loaded by the system are **visible**. There is a **delay** in loading the packages in Present and Proposed table. The delay issue will be addressed in a future release.
76861	Select All in combination with pagination will delete the previous selection	An issue related to applications containing more than 50 packaged medicinal products has been fixed. It is now possible to select all packages for all selected medicinal products
93686	Friendly name validates at 100 chars but fails at 80 chars already	A technical issue (bug) detected on the background preventing finalisation of the eAF with a Friendly name exceeding 8 characters has been fixed.

Known Issues

ID	Component	Short description
16208	Human Variations eAF	Select All button must select all the available records in Available Products table and Packaged Products table
11086	PLM Portal	Copy application feature not available yet

246	Human Variations eAF	It is not possible to change the 'Friendly name'
25715	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 Variations eAF	Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional Information section
37644	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)
38300	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
23547	Human Variations eAF	Procedural information: Some mandatory fields are not mandatory in the form
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
29121	Human Variations eAF	Improve communication – guidance and support page
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal

26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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23851	Human Variations eAF	Search on present-proposed disappearing
23896	Human Variations eAF	Error after wrong date format for Implementation date
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
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
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
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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~~
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.7 (Release date 17/04/2023)

Version Goal: PLM Portal bug fix release

Date: 17/04/2023

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 1.0.1.7	This release note is for the BUGFIX version 1.0.1.7 release go-live 17/04/2023
Update of the human readable pdf export	PDF version 2.0.5.1	This release note is for the BUGFIX version 2.0.5.1 release go-live 20/02/2023
Implementation of the FHIR xml	FHIR XML 1.1.2.0	

Issues fixed in this version

ID	Description	Comments
37806	Enable search of EU Orphan designations using the EU Orphan Designation number(s)	It is now easier to add the EU Orphan designation numbers into the section 4a on Information relating to orphan market exclusivity
42683	The ATC code should also display the ATC code group in the PDF	The pdf output now also displays the ATC code group in addition to the ATC code.
59912	Regression: too many options visible in the dropdown for applicant contributor	The number of features/functions available for Contributor is now limited in the list of applications dropdown menu (no functional change)

Known Issues

ID	Component	Short description
11086	PLM Portal	Copy application feature not available yet
246	Human Variations eAF	It is not possible to change the 'Friendly name'
25715	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 Variations eAF	Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional Information section

37644	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)
38300	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
23547	Human Variations eAF	Procedural information: Some mandatory fields are not mandatory in the form
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
~~23910~~	~~Human Variations eAF~~	~~eAF allows only two signatories~~
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
29121	Human Variations eAF	Improve communication – guidance and support page
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal
26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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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
23915	Human Variations eAF	Organisation information - parent organisation label does not match
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23931	Human Variations eAF	Double-clicking Save button for Change(s) Scope creates duplicates
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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
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
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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.6 (Release date 21/02/2023)

Version Goal: PLM Portal bug fix release

Date: 21/02/2023

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 1.0.1.6	This release note is for the BUGFIX version 1.0.1.6 release go-live 21/02/2023
Update of the human readable pdf export	PDF version 2.0.5.1	This release note is for the BUGFIX version 2.0.5.1 release go-live 20/02/2023

Update of the human readable pdf export	PDF Version 2.0.2.2* *Please note that the newly introduced 4th number refers to technical changes in the pdfgen. These do not refer to change in the pdf output form used by business users.	This release note is for the BUGFIX version 2.0.2 release go-live 06/02/2023
Implementation of the FHIR xml	FHIR XML 1.1.2.0	**Release go-live 10/02/2023:** • ASMF/DUNS/Telephone/Email mapping***** (**36110**) • Limit width of free text fields***** (**24565**) • Ingredient/Ingredient Strength/Ingredient Documentation FHIR refactoring (**30382**/**30383**/**30387**) • Attach every DeviceDefinition to a Medicinal Product (**38537**) • Add the Source ID to the ATC while keeping the ATC name as well (**38779**) • Minor fixes to the Device variation as new edge-cases were tested (**37124**/**38274**)

Issues fixed in this version

ID	Description	Comments
22398	Present and Proposed section: • ASMF number and DUNS number fields missing from the Web UI. • Telephone number and email address fields added for organisations entered/selected for changes in present and proposed	Input fields for the ASMF number and DUNS number have been added to the web UI of eAF. When added in the form, the ASMF numbers will be presented as a part of the present and proposed table, not as a separate field below all present and proposed fields like in the interactive pdf. The DUNS number field will only be displayed in the pdf if value is added to that field in the web eAF. The DUNS number is displayed as a part of the organisational information and not as a separate field below all present and proposed fields like in the interactive pdf.

38757	Application Forms view – Label change to the drop down options	In the application forms list view, the menu options on the right hand side dropdown selection now indicate 'Coming soon' for those features that are not yet available (for example Copy Application).
40214	Image resize issue	The images are now displayed in a legible format in the present and proposed fields. The fields in present and proposed can be now used as per normal.
27729	Clicking 'validate' immediately after clicking 'save' throws an error (RPI cannot be blank for CAP products).	The error message is no longer displayed when the RPI is present and even if the 'validate' button is clicked before the packages are loaded.
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
42871	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.	The mandatory tick boxes are now available in Declaration section when expected and no validation error is displayed.
37507	Correct typos – present and proposed section: Pharmacovigilance'	Typo has been corrected in the dropdown list of proposed changes

Known Issues

ID	Component	Short description
Known limitation	PLM Portal	Copy application feature not available yet
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 Variations eAF	Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional Information section

37644	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)
38300	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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
37806	Human Variations eAF	Enable search of EU Orphan designations using the EU Orphan Designation number(s)
23547	Human Variations eAF	Procedural information: Some mandatory fields are not mandatory in the form
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
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
29109	Human Variations eAF	Improve communication – 'news' tile on homepage
29121	Human Variations eAF	Improve communication – guidance and support page
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal
26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly

23910	Human Variations eAF	Inconsistent button behaviour 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
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
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
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
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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.4 (Release date 23/01/2023)

Version Goal: PLM Portal bug fix release

Date: 23/01/2023

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 1.0.1.4	This release note is for the BUGFIX version 1.0.1.4 release go-live 23/01/2023

Update of the human readable pdf export	PDF Version 2.0.2.2* *Please note that the newly introduced 4th number refers to technical changes in the pdfgen. These do not refer to change in the pdf output form used by business users.	This release note is for the BUGFIX version 2.0.2 release go-live 23/01/2023

Issues fixed in this version

ID	Description	Comments
24184 – web eAF	Add a link to the Guidance for applicants on precise scope	The Guidance for applicants for the preparation of the 'precise scope' section of the variation application form is now available via a link in the Precise Scope section (via 'info' button)
35219 – web eAF	Proposed Changes Section: Upload Image Error in Rich Text Box Field	It is now possible to include images in the Present and Proposed fields (the production issue has been fixed).
24565 – web eAF	Limit width of free text fields	The images are now displayed in more legible format in the present and proposed fields.
25713 – web eAF	Info text for commercially confidential data is incorrect	The information text explaining the details related to access management in relation to CCI have been clarified and corrected.

Known Issues

ID	Component	Short description
Known limitation	PLM Portal	Copy application feature not available yet
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 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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
27729	Human Variations eAF	Clicking 'validate' immediately after clicking 'save' throws an error (RPI cannot be blank for CAP products). This error message is incorrect and doesn't at all have anything to do with RPI.
23547	Human Variations eAF	Procedural information: Some mandatory fields are not mandatory in the form
22398	Human Variations eAF	Present and Proposed section: ASMF number and DUNS number fields missing from the Web UI. **Workaround**: 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
15504	Human Variations eAF	Deleted product package details are still appearing in Proposed changes section
29109	Human Variations eAF	Improve communication – 'news' tile on homepage

29121	Human Variations eAF	Improve communication – guidance and support page
35130	Human Variations eAF	Improve communication – change guidance documentation on login page from IRIS to PLM Portal
26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour 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
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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.3 (Release date 12/12/2022)

Version Goal: Go-Live PLM Portal

Date: 12/12/2022

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 1.0.1.3	This release note is for the BUGFIX version 1.0.1.3 release go-live 12/12/2022

Issues fixed in this version

ID	Description	Comments
23987 – web eAF	Grouped variations including line extension	It is now possible to indicate that the variation contains a line extension also for those variations where only a single scope is selected.
27565 – web 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.	The mandatory tick boxes are now available in Declaration section when expected and no validation error is displayed.
22013 – web eAF	Updated text for the 'no address change' in the declaration in present and proposed section	The text in the web eAF has been aligned to correspond with the updated text as per pdf eAF release on 14th 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
22571 – web eAF	Medical Device: Manufacture of the device and Notified Body should be optional	The Manufacturer and the Notified body fields are now optional.
24810 – web eAF	Email template populate incorrectly after sending notification to co-author from different organisation	The correct notification template is now sent by the system when sent by the user.
25511	Fix typos on homepage	Typos of the PLM Portal homepage have been fixed
24533 – web eAF	Update Chatbot content and Look & Feel	The chatbot reflects the latest guidance content.
25435 – web eAF	Change internal chatbot div, css and js code	The chatbot is no longer obscuring text on the form/PLM portal.

Known Issues

ID	Component	Short description
Known limitation	PLM Portal	Copy application feature not available yet
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 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/has only limited procedures available for some products. **Workaround**: use the +Add to manually add other ongoing applications
22398	Human Variations eAF	Present and Proposed section: ASMF number and DUNS number fields missing from the Web UI. **Workaround**: 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 behaviour 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
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
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

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	Although the selected Medicinal Products were taken into account in the PDF, the packaged products weren't listed correctly. This fix is visible in

	ones in the FHIR Message (XML)	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
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 finalisation of the form. **Note:** This does not result in business validation error as this is a known bug in the form.
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 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
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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 xml	FHIR XML 1.0.2.0	This release note is for the BUGFIX version 1.0.2.0 release go-live 16/11/2022

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 | Remaining known issue: Validation error in product selection is incorrectly showing up if 'Validation' is pressed immediately after Saving.

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. |
|---|---|---|
| 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 eAF | Validation error message is displayed in proposed changes section after combining scopes and packaged medicinal products | Scrambled validation error message is not be shown 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 14th 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	• 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 finalisation of the form. **Note:** This does not result in business validation error as this is a known bug in the form.

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 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)'

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
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
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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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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

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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