13 December 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.

EMA is pleased to announce another for the web-based Human Variation application forms, the availability of the non-Centrally Authorised Products (non-CAPs) in the PLM Portal eAF from **14th October 2024**. The users should note that while the non-CAP products are available, applications created in the PLM Portal cannot yet be submitted to the NCAs for non-EMA led variation applications. The web-based eAF can be used for EMA led worksharing applications.

The formal **transition period** will start when all critical issues have been addressed and all 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 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: 1.1.1.0 (Release date 09/12/2024)

Version Goal: Updated present and proposed section, further variation regulation updates, multiselect application contact person and bug fixes

Date: 09/12/2024

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 1.1.1.0	This release note is for the version 1.1.1.0 release go-live 09/12/2024

New stories released in this version

ID	Description	Comments
222840	Procedural information: Change in calculation for type of application (for CAPs)	The business rules related to the calculation of type of application have been updated to correctly reflect single/grouping/workharing/super-grouping
210325	Present and Proposed section – Implement new functionality	**Partial implementation** of the improved Present and Proposed section with new User Interface (UX) designs **Known issues and bugs:** • Select product packages for proposed changes sub window: the filtering is limited and when filters are used top level selection doesn't work • Add Package function is 'hidden' inside the 'Edit' view of package and scope summary view • Section title should be optional field • Adding present and proposed organisation before saving the text changes in the present and proposed fields will lead to losing of the text. **Note:** when adding

		organisations, **please add the organisation first** or use the declaration button to indicate there are no changes to organisations to allow saving of the present and proposed text fields
		• Saving closes the present and proposed windows and takes the user back to the Proposed Changes home page
		• *Previous*, *Next*, *Copy*, *Separate* and *Outline* buttons and the dropdown menu for the selection of the Present/Proposed or Present+Proposed fields are non-functional (do not work)
		• It is not possible to view multiple sections of the present and proposed fields at the same time
173444	Application Contact 'Member State' multi-selection for non-CAPs	For non-CAP variations it is now possible to indicate the same application contact person using new multiselect option for member state
217411	Updates related to 'Parallel Procedures' section/other changes reflecting amended variation regulation (e.g. mandatory worksharing)	The business rules have been updated and the Declaration on parallel variations has been updated. **Note:** • Discrepancy in the text between UI and pdf export will be corrected in a future release) • The updates relate to the amended Variation Regulation entering into force from 1st January 2025 • The new Declaration and the note field relate to the '**Mandatory worksharing**' procedures where the applicant needs to declare the parallel variations of the same scope for other products (justification why the applicant chose not to do a worksharing, but a separate variation). Please note that when the tickbox is selected, the product grid should not appear.

Coming soon/we are currently working on

ID	Short description
Various	Performance improvements e.g. Finalisation section – implementation postponed
207009	Proof of Payment section: business rules fixes and non-CAP procedure support Expected deployment: Q1 2025
210325	Present and Proposed section re-design and performance improvements implementation of the remaining features/functions. Expected deployment: Q1 2025
	eAF integrity stamp: Upon Finalising the application form, a digital signature confirming that the form has been exported from the PLM Portal is placed on the pdf export by the system Expected deployment: Q1 2025
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Known Issues and Limitations

ID	Short description
185709	Allow the selection of an 'Alternative' organisation name in the eAF (displayed on the pdf)
217411	Updates related to 'Parallel Procedures' section/other changes reflecting amended variation regulation (e.g. mandatory worksharing) – Harmonisation section is currently not displayed in the web UI
Known issue	When exporting the pdf, the export is intermittently not triggered on the first attempt but might require multiple attempts before succeeding.
Known issue	Cyrillic characters showing '?' in the full name field – this is not a data issue but reflecting data from xEVMPD. This needs to be corrected by the respective MAHs with new version of product to be sent to xEVMPD.
Known issue	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 issue	In Medical Device section the 'EU authorised representative' option is missing

Known issue	The selections from the Medical Device section 4d. are not correctly reflected in the pdf export in some cases. **Please note:** for variation applications indicating a change in the device in section 4d. please consider using the interactive pdf eAF.
Known issue	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish
Known issue	Products authorised in Belgium: The full name of product is displayed (randomly) either in Flemish, French or German
Known issue	In section Type(s) of Change(s) – scope selection: known issue where selection of all conditions and documentations using the high level tickbox will result an error message saying all conditions and documentations should be selected or note should be provided.
Known limitation	23965 - Conditions and documentation are presented in different order from the variation classification guideline
Known limitation	Concurrent users – there is currently a limitation in the system where 2 or more users can work at the same time in the same application form, however, the changes cannot be saved at the same time and this could lead into data loss by one of the concurrent users. It is strongly recommended to organise a workflow internally to avoid any data loss.
Known limitation	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 – will be resolved with the new present and proposed design
Known limitation	22845 – Deletion of Application Form is not yet available
Known limitation	23545 - Performance issues Number of sections take very long to open or to display the changes/selections made by the user; for example in Finalisation section, most functions take much longer than acceptable e.g. displaying the parallel procedures section can take up to 1 minute etc.
Known limitation	Proof of Payment section: It is currently not possible to indicate different details for non-CAP WS variations for countries with pre-payment and countries with billing details
Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Product data quality/duplication of data	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: 1.1.0.3 (Release date 25/11/2024)

Version Goal: New variation regulation updates and bug fixes

Date: 25/11/2024

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 1.1.0.3	This release note is for the version 1.1.0.3 release go-live 25/11/2024

Issues fixed in this version

ID	Description	Comments
207011	New variation regulation e.g. super-grouping rules for non-CAPs	The business rules related to the super-groupings have been updated to reflect the amended variation regulation
137105	Contact person tooltip for CAPs	For CAPs, the instructions on the form on how to use the contact person field for procedures managed in IRIS were updated
218049	Bug – newly added package	A bug related to newly added Packaged Product not showing up in PDF was fixed
211888	Error message updated	The error message shown when there are product data issues with the selected products was updated.

Coming soon/we are currently working on

ID	Short description
173444	Application contact for non-CAPs should be multiselect. It is currently not possible to select the same contact person for more than 1 Member State, in case the same contact person if used for multiple member states the section needs to be repeated.

217411	Updates related to 'Parallel Procedures' section/other changes reflecting amended variation regulation (e.g. mandatory worksharing)
Various	Performance improvements e.g. Finalisation section
207009	Proof of Payment section: business rules fixes and non-CAP procedure support Expected deployment: Q1 2025
Various	Present and Proposed section re-design Expected deployment: Q1 2025
	eAF integrity stamp: Upon Finalising the application form, a digital signature confirming that the form has been exported from the PLM Portal is placed on the pdf export by the system Expected deployment: Q1 2025
Various	Analysis of the next set of structured changes e.g. packages, manufacturers etc

Known Issues and Limitations

ID	Short description
185709	Allow the selection of an 'Alternative' organisation name in the eAF (displayed on the pdf)
Known issue	When exporting the pdf, the export is intermittently not triggered on the first attempt but might require multiple attempts before succeeding.
Known issue	Cyrillic characters showing '?' in the full name field – this is not a data issue but reflecting data from xEVMPD. This needs to be corrected by the respective MAHs with new version of product to be sent to xEVMPD.
Known issue	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 issue	In Medical Device section the 'EU authorised representative' option is missing
Known issue	The selections from the Medical Device section 4d. are not correctly reflected in the pdf export in some cases. **Please note:** for variation applications indicating a change in the device in section 4d. please consider using the interactive pdf eAF.
Known issue	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish
Known issue	Products authorised in Belgium: The full name of product is displayed (randomly) either in Flemish, French or German

Known issue	In section Type(s) of Change(s) – scope selection: known issue where selection of all conditions and documentations using the high level tickbox will result an error message saying all conditions and documentations should be selected or note should be provided.
Known limitation	23965 - Conditions and documentation are presented in different order from the variation classification guideline
Known limitation	Concurrent users – there is currently a limitation in the system where 2 or more users can work at the same time in the same application form, however, the changes cannot be saved at the same time and this could lead into data loss by one of the concurrent users. It is strongly recommended to organise a workflow internally to avoid any data loss.
Known limitation	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 – will be resolved with the new present and proposed design
Known limitation	22845 – Deletion of Application Form is not yet available
Known limitation	23545 - Performance issues Number of sections take very long to open or to display the changes/selections made by the user; for example in Finalisation section, most functions take much longer than acceptable e.g. displaying the parallel procedures section can take up to 1 minute etc.
Known limitation	Proof of Payment section: It is currently not possible to indicate different details for non-CAP WS variations for countries with pre-payment and countries with billing details
Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Product data quality/duplication of data	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: 1.1.0.2 (Release date 11/11/2024)

Version Goal: PLM Portal bug fix release

Date: 11/11/2024

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 1.1.0.2	This release note is for the version 1.1.0.2 release go-live 11/11/2024

Issues fixed in this version

ID	Description	Comments
195239	Application list page (UI design)	The new User interface design has been implemented on the application list page

Coming soon/we are currently working on

ID	Short description
173444	Application contact for non-CAPs should be multiselect. It is currently not possible to select the same contact person for more than 1 Member State, in case the same contact person if used for multiple member states the section needs to be repeated.
Various	Performance improvements e.g. Finalisation section
Various	Present and Proposed section re-design Expected deployment: end of Q4
207011	New variation regulation e.g. super-grouping rules for non-CAPs Expected deployment: before end of Q4
207009	Proof of Payment section: business rules fixes and non-CAP procedure support

	Expected deployment: end of Q4
	eAF integrity stamp: Upon Finalising the application form, a digital signature confirming that the form has been exported from the PLM Portal is placed on the pdf export by the system
185709	Allow the selection of an 'Alternative' organisation name in the eAF (displayed on the pdf)
Various	Analysis of the next set of structured changes e.g. packages, manufacturers etc

Known Issues

ID	Short description
Known limitation	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 issue	Cyrillic characters showing '?' in the full name field – this is not a data issue but reflecting data from xEVMPD. This needs to be corrected by the respective MAHs with new version of product to be sent to xEVMPD.
Known limitation	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	In Medical Device section the 'EU authorised representative' option is missing.
Known limitation	22845 – Deletion of Application Form is not yet available
Intermitted known issue	25400 - Incorrect calculation of number of selected scopes in the summary page
Known limitation	23965 - Conditions and documentation are presented in different order from the variation classification guideline
Known issue	In section Type(s) of Change(s) – scope selection: known issue where selection of all conditions and documentations using the high level tickbox will result an error message saying all conditions and documentations should be selected or note should be provided.
Known limitation	Concurrent users – there is currently a limitation in the system where 2 or more users can work at the same time in the same application form, however, the changes cannot be saved at the same time and this could lead into data loss by one of the concurrent users. It is strongly recommended to organise a workflow internally to avoid any data loss.
Known limitation	23545 - Performance issues Number of sections take very long to open or to display the changes/selections made by the user; for example in Finalisation section, most functions take much longer than acceptable e.g. displaying the parallel procedures section can take up to 1 minute etc.

Known limitation	Proof of Payment section: It is currently not possible to indicate different details for non-CAP WS variations for countries with pre-payment and countries with billing details
Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Known issue	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish
Known issue	Products authorised in Belgium: The full name of product is displayed (randomly) either in Flemish, French or German
Product data quality/duplication of data	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: 1.1.0.1 (Release date 28/10/2024)

Version Goal: PLM Portal bug fix release

Date: 28/10/2024

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 1.1.0.1	This release note is for the version 1.1.0.1 release go-live 28/10/2024

Issues fixed in this version

ID	Description	Comments
192580 198781	User Interface Design and UI Improvements	Home page User Interface improvements and other general rectifications
197976	Prevent parallel application cloning	Once the cloning of an application starts, another clone cannot be triggered. If the user tries to clone an application that is already in a cloning process, a pop-up message will appear on the screen
206642	Clone application improvements	When an application is cloned with the change of MAH, the products and attributes derived from products are erased.
206987	IRIS link added to PLM Portal	A link to IRIS Portal was added to the top right menu of the PLM Portal, for quicker access to IRIS.
23546	Orphan Drug improvements	In the Orphan Drug section in Additional Information, multiple designations can be added
209832	Nullified products filtered out	The Nullified products do not appear anymore in the selection of products
182808	Bug – Type(s) of changes identifier column	The Identified column in Type(s) of Changes is now shown in the correct position

195016	Bug – Signatory	A bug related to saving the signatory was fixed
205779	Bug (FHIR XML) – Incomplete scopes not added to the XML	A bug related to the presence of Incomplete scopes in the FHIR XML was fixed
211947	Bug – Type of change saving	A bug related to saving after adding a scope was fixed

Coming soon/we are currently working on

ID	Short description
173444	Application contact for non-CAPs should be multiselect. It is currently not possible to select the same contact person for more than 1 Member State, in case the same contact person if used for multiple member states the section needs to be repeated.
Various	Performance improvements e.g. Finalisation section
Various	Present and Proposed section re-design

Expected deployment: end of Q4 |
| 207011 | New variation regulation e.g. super-grouping rules for non-CAPs

Expected deployment: before end of Q4 |
| 207009 | Proof of Payment section: business rules fixes and non-CAP procedure support

Expected deployment: end of Q4 |
	eAF integrity stamp: Upon Finalising the application form, a digital signature confirming that the form has been exported from the PLM Portal is placed on the pdf export by the system
185709	Allow the selection of an 'Alternative' organisation name in the eAF (displayed on the pdf)
Various	Analysis of the next set of structured changes e.g. packages, manufacturers etc

Known Issues

ID	Short description
Known limitation	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 issue	Cyrillic characters showing '?' in the full name field – this is not a data issue but reflecting data from xEVMPD. This needs to be corrected by the respective MAHs with new version of product to be sent to xEVMPD.
Known limitation	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	In Medical Device section the 'EU authorised representative' option is missing.
Known limitation	22845 – Deletion of Application Form is not yet available
Intermitted known issue	25400 - Incorrect calculation of number of selected scopes in the summary page
Known limitation	23965 - Conditions and documentation are presented in different order from the variation classification guideline
Known issue	In section Type(s) of Change(s) – scope selection: known issue where selection of all conditions and documentations using the high level tickbox will result an error message saying all conditions and documentations should be selected or note should be provided.
Known limitation	Concurrent users – there is currently a limitation in the system where 2 or more users can work at the same time in the same application form, however, the changes cannot be saved at the same time and this could lead into data loss by one of the concurrent users. It is strongly recommended to organise a workflow internally to avoid any data loss.
Known limitation	23545 - Performance issues Number of sections take very long to open or to display the changes/selections made by the user; for example in Finalisation section, most functions take much longer than acceptable e.g. displaying the parallel procedures section can take up to 1 minute etc.
Known limitation	Proof of Payment section: It is currently not possible to indicate different details for non-CAP WS variations for countries with pre-payment and countries with billing details
Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Known issue	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish
Known issue	Products authorised in Belgium: The full name of product is displayed (randomly) either in Flemish, French or German
Product data quality/duplication of data	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: 1.1 (Release date 14/10/2024)

Version Goal: PLM Portal bug fix release

Date: 14/10/2024

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 1.1	This release note is for the version 1.1 release go-live 14/10/2024

Issues fixed in this version

ID	Description	Comments
	Non-Centrally Authorised Products (non-CAPs) go-live in the web-based eAF	Products authorised through Mutual Recognition Procedure (MRP), Decentralised Procedure (DCP) and National Procedures (NP) are now available in the eAF for familiarisation and training purposes. Please note that it is not yet possible to submit eAFs generated form the PLM Portal to NCAs. The web-based application form **can be used** for **EMA-led worksharing** applications containing CAPs and **non-CAPs**.
175342	RMS/CMS selection of single MRP product	It is now possible to correctly indicate the Reference Member State for products authorised through MRP procedure.
207814	Part 2: Filter out CAPs that do not have authorisation country EU (Norway, Iceland, Liechtenstein) on the parallel procedures and orphan product selection tables.	Ther CAPs are showing only once also in the product selection windows in parallel procedures section and in the Orphan products section. The entries for Norway, Iceland and Lichtenstein are not visible anymore.
198291	Performance – Optimise indexing in tables	The performance has been improved in areas where tables are shown.

23849	Annexed documents section: External links in the help text cannot be selected easily	The external links in the help text can now be selected easily.
202259	Checkbox on 'View selected products' not functional	The checkbox in the selected products view can now be ticked/unticked as needed.
204369	Regression error – error 500 shown in production	Production bug preventing the use of the forms (error Status 500) was fixed in production on the day it occurred.
205988	Product selection not working properly	Partially fixed: please note that while majority of the filters now work as expected, there is still a bug in the authorised dose form filter. You might need to refresh to restart search. We are working to fix this.

Coming soon/we are currently working on

ID	Short description
209832	Filter out nullified products: this user story will remove number of products that appear as duplicates for the end user in product selection. The nullified products in currently causing an incorrect error message to be displayed (error message refers to product/scope combination) and in some cases these nullified products preventing the use of the web-based form. Expected fix deployment date: 28th October 2024
173444	Application contact for non-CAPs should be multiselect. It is currently not possible to select the same contact person for more than 1 Member State, in case the same contact person if used for multiple member states the section needs to be repeated.
Various	Performance improvements e.g. Finalisation section
Various	Present and Proposed section re-design Expected deployment: end of Q4
207011	New variation regulation e.g. super-grouping rules for non-CAPs Expected deployment: before end of Q4
207009	Proof of Payment section: business rules fixes and non-CAP procedure support Expected deployment: end of Q4
	eAF integrity stamp: Upon Finalising the application form, a digital signature confirming that the form has been exported from the PLM Portal is placed on the pdf export by the system

185709	Allow the selection of an 'Alternative' organisation name in the eAF (displayed on the pdf)
Various	Analysis of the next set of structured changes e.g. packages, manufacturers etc

Known Issues

ID	Short description
Known limitation	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 issue	Cyrillic characters showing '?' in the full name field – this is not a data issue but reflecting data from xEVMPD. This needs to be corrected by the respective MAHs with new version of product to be sent to xEVMPD.
Known limitation	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	In Medical Device section the 'EU authorised representative' option is missing.
Known limitation	22845 – Deletion of Application Form is not yet available
Intermitted known issue	25400 - Incorrect calculation of number of selected scopes in the summary page
Known limitation	23965 - Conditions and documentation are presented in different order from the variation classification guideline
Known issue	In section Type(s) of Change(s) – scope selection: known issue where selection of all conditions and documentations using the high level tickbox will result an error message saying all conditions and documentations should be selected or note should be provided.
Known limitation	Concurrent users – there is currently a limitation in the system where 2 or more users can work at the same time in the same application form, however, the changes cannot be saved at the same time and this could lead into data loss by one of the concurrent users. It is strongly recommended to organise a workflow internally to avoid any data loss.
Known limitation	23545 - Performance issues Number of sections take very long to open or to display the changes/selections made by the user; for example in Finalisation section, most functions take much longer than acceptable e.g. displaying the parallel procedures section can take up to 1 minute etc.
Known limitation	Proof of Payment section: It is currently not possible to indicate different details for non-CAP WS variations for countries with pre-payment and countries with billing details
Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Known issue	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish

Known issue	Products authorised in Belgium: The full name of product is displayed (randomly) either in Flemish, French or German
Product data quality/duplication of data	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: 1.0.1.19 (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

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: 1.0.1.17 (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	In the additional details, for "Type IB and Type II variations - Paediatric Requirements", the validation

	number/Competent Authority is required."	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

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: 1.0.1.16 (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

		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
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: 1.0.1.15 (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
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: 1.0.1.14 (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

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)'
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: 1.0.1.12 (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

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: 1.0.1.10 (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
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
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: 1.0.1.7 (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
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
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
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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

		the PDF version 2.0.2. There is no change to FHIR version.
	ones in the FHIR Message (XML)	
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
25269	Human Variations eAF	Product select screen shows 0/0 product presentation

25301	Human Variations eAF	Precise scope and background for information section not saved
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

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

Version Goal: Go-Live PLM Portal

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

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.1.1	This release note is for the BUGFIX version 1.0.1.1 release go-live 14/11/2022
Implementation of the human readable pdf export	PDF Version 2.0.1	This release note is for the BUGFIX version 2.0.1 release go-live 17/11/2022
Implementation of the FHIR 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
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25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
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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
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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
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24006	PLM Portal	Refresh button producing error on Application list view
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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

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

Known Issues

ID	Component	Short description
Known limitation	PLM Portal	Copy application feature not available yet
Known limitation	Human Variations eAF	Cannot select 'includes line extension' when single scope added
Known limitation	Human Variations eAF	It is not possible to change the 'Friendly name'
Known limitation	Human Variations eAF	Form cannot be used for variations that add new presentation

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

23545	PLM Portal	Performance issues
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily
23851	Human Variations eAF	Search on present-proposed disappearing
23896	Human Variations eAF	Error after wrong date format for Implementation date
23912	Human Variations eAF	Menu handling checkbox - Additional information does not disappear where it should have
23913	Human Variations eAF	Precise Scope & Background Info Pop-Up
23915	Human Variations eAF	Organisation information - parent organisation label does not match
23923	Human Variations eAF	Drop down list member state country doesn't open - intermittent
23931	Human Variations eAF	Double-clicking Save button for Change(s) Scope creates duplicates
23961	PLM Portal	Drop-down invisible in Application Forms overview
23963	Human Variations eAF	Changes Implementation Date issue
23963	Human Variations eAF	Finalisation: Statement in Annexed document and Declaration Section in random order in DADI
23965	Human Variations eAF	Conditions and documentation in DADI are not in the same order as in the variation classification guideline
23966	Human Variations eAF	Not possible to paste an image to the Present and Proposed fields in the Present and Proposed Value(s) tab
23967	Human Variations eAF	Finalisation section - Proof of payment - able to select either Yes or NO
23968	Human Variations eAF	Hyphenations are incorrect in tab type of changes, in the view scope and description and in the view conditions and documentation section
23969	Human Variations eAF	Cannot select more than one organisation in Proposed Organisation field
23971	Human Variations eAF	Proposal for Organisation Details – Split Text

23974	Human Variations eAF	Suggestion - Scope section - Information is not displayed in a user-friendly manner.
24006	PLM Portal	Refresh button producing error on Application list view
24810	PLM Portal	Email template populate incorrectly after sending "Notify" email to co-author
24905	PDF	Country name shown is long version in PDF
24907	Human Variations eAF	Select all checkbox does not "Select All" in "Proposed Changes" section
25269	Human Variations eAF	Product select screen shows 0/0 product presentation
25301	Human Variations eAF	Precise scope and background for information section not saved
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form