

25 June 2025

PLM Portal eAF - Release Notes

Important notice 29 April 2025:

Corrupted products issue: A small number of products are affected by a synchronisation issue with PMS and the forms where they are used cannot be exported and finalised. Once added the products in the eAF, export the form and should you see the message "Data refresh cannot be completed. Aborting the operation. Please retry again.", please raise a ticket with Service Desk and the team will assess if it can be fixed. In some cases, should that not be possible, you might need to use the interactive PDF instead. The teams are working on fixing this issue and a new message will be published once it is resolved.

Important notice 24 June 2025:

Missing products issue: Approximately 19.000 non-CAP products are affected by a PMS defect and are currently missing from the PLM Portal eAF. This issue concerns products for which the authorised dose form is coming from a specific list e.g. combined dose form list. Unfortunately, the PLM eAF cannot be used until this issue has been addressed by PMS.

Duplicate products issue: (affecting CAPs and non-CAPs): due to data errors coming from xEVMPD/PMS some packaged medicinal products are currently visible under 2 different medicinal products. This will cause an issue in the eAF and user will not be able to continue the use of the web based eAF until this data error is corrected.

EMA has launched the web-based Human Variations electronic application form (eAF) for Centrally Authorised Products (CAPs) on **4th November 2022**, on the [Product Lifecycle Management \(PLM\) Portal](#). EMA was collaborating with the UNICOM consortium to develop the human variation form

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.

Following the launch of **optional use for all EU products and procedures** in February 2025, EMA now **recommends the use** of the [PLM Portal](#) web-based eAF **for all non-CAPs human variations**, where possible. This is aligned with the [timeline](#) and the roadmap towards mandatory use of the PLM Portal web-based eAF for all human variations. Please follow user guidance, the current release notes and EMA announcements in relation to any known technical limitations.

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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. It also hosts the user interface for [product management service \(PMS\) data](#) and the interface to provide data for [electronic Product Information \(ePI\)](#). The PLM Portal will further develop over time to inform and support you in the use of these services.

Versioning: Please note that the PLM Portal web-based pdf export is indicated with version number 2.x and this version is comparable to the v1.27.x.x of the interactive pdf eAF from eSubmission website.

This document lists and briefly describes the new features and fixed issues included in the release of the PLM Portal. The most recent release appears first.

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About this Document

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

The most recent release appears first.

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

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

For additional information on the PLM portal see this:

- User guidance recording on the PLM Portal:
- User guidance documentation on the 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: 1.2.0.7 (Release date 23/06/2025)

Version Goal: UX/UI Design, Bug fixes

Date: 23/06/2025

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 1.2.0.7	This release note is for the version 1.2.0.7 release go-live 23/06/2025

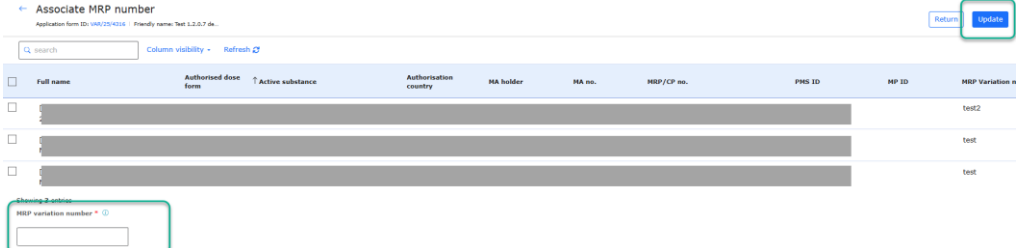
New stories released in this version

ID	Description	Comments
192587	UI Design - Finalisation	The new UI design is implemented in the "Finalisation" section. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.
251258	[Bug] Finalisation section - Declaration of applicant section	In the finalisation section, declaration of applicant section now is displayed for Type IB unforeseen and Type II Art. 29
242270	Procedural Information Calculation for all Procedure Types	The eAF can be used for all procedure types which are not categorised as CAP, NAP, MRP/DCP (e.g. homeopathic). A bug which prevented these products to be shown in the PDF was fixed.
Known issue	AIFA update	The Italian Medicines Agency (AIFA) applied worked on a limitation which prevented the acceptance of the PLM Portal eAFs. Now the forms can be submitted to AIFA.
Known issue	The section 4a (Orphan) and 4b (paediatric) are not reflected correctly in the exported pdf.	The PLM Portal eAF can now be used for variations using sections 4a and 4b.

Coming soon/we are currently working on

ID	Short description
UX/UI	The Design of the read-only pages will be replaced

Known Issues and Limitations

ID	Short description
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Variations for ATC code must be done in the free text fields in Present and Proposed section
Known issues	<p>The "Update" button for the "Associate MRP button" window is temporarily showing at the top right of the page, instead of its correct position (bottom left).</p>  <p>The button will be moved back in a future release.</p>
Known issues	A small number of products are affected by a synchronisation issue with PMS and the forms where they are used cannot be exported and finalised. Once added the products in the eAF, export the form and should you see the message "'Data refresh cannot be completed. Aborting the operation. Please retry again.'", please raise a ticket with Service Desk and the team will assess if it can be fixed. In some cases, should that not be possible, you might need to use the interactive PDF instead. The teams are working on fixing this issue and a new message will be published once it is resolved.
Known issue	When exporting the pdf, the export is intermittently not triggered on the first attempt but might require multiple attempts before succeeding.
xEVMPD data 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 Workaround: use the interactive pdf eAF for variations where in section 4d option 'EU authorised representative option needs to be selected

Known issue	<p>The selections from the Medical Device section 4d. are not correctly reflected in the pdf export in some cases.</p> <p>Please note: for variation applications indicating a change in the device in section 4d. please consider using the interactive pdf eAF.</p>
Known limitation	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish
Known limitation	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 intermitted 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	22845 – Deletion of Application Form is not yet available
Known limitation	<p>23545 - Performance issues</p> <p>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.</p>
Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	<p>Present and Proposed section - implementation of the remaining features/functions.</p> <p>Expected deployment: Q3-Q4 2025</p>
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device
Known limitation	If a product has multiple dose authorisation forms, only one appears in eAF.

Version: 1.2.0.6 (Release date 10/06/2025)

Version Goal: Performance improvements, bug fixes

Date: 10/06/2025

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 1.2.0.6	This release note is for the version 1.2.0.6 release go-live 10/06/2025

New stories released in this version

ID	Description	Comments
239420	[Performance] Optimise product selection save process	A new feature was introduced that only allows to select 50 products at one time. This will address some of the performance issues for la
227592 230235	[Performance] Optimize PLM Portal	Technical performance improvements (odatafilter)
241946	[Bug] Info relating to orphan market exclusivity	A bug related to Additional information: Info relating to orphan market exclusivity (selection of the designated Orphan medicinal product(s) been granted a marketing authorisation in the EU) was fixed
39391	[Bug] PLM Portal timezone	A bug related to the timezones was fixed (the same timezone is used throughout the portal)
248530	[Bug] Proposed Changes section	A bug related to proposed changes section showing validation error while all products and scopes are associated was fixed
248541	[Bug] Number of selected packages after present/proposed is created	A bug related to the number of selected packages not updating when products are added after present/proposed change creation was fixed

Coming soon/we are currently working on

ID	Short description
UI Design	UI Design implementation to continue for the rest of the application and for the sections that were not finalised

Known Issues and Limitations

ID	Short description
Known issues	A small number of products are affected by a synchronisation issue with PMS and the forms where they are used cannot be exported and finalised. Once added the products in the eAF, export the form and should you see the message ""Data refresh cannot be completed. Aborting the operation. Please retry again.", please raise a ticket with Service Desk and the team will assess if it can be fixed. In some cases, should that not be possible, you might need to use the interactive PDF instead. The teams are working on fixing this issue and a new message will be published once it is resolved.
Known issue	The Italian Medicines Agency (AIFA) is currently working on a limitation which prevents the acceptance of the PLM Portal eAFs. The estimated date for the fix is end of June. Follow the EMA release notes for further updates.
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Variations for ATC code should be done in the free text fields in Present and Proposed section
Known issue	The section 4a (Orphan) and 4b (paediatric) are not reflected correctly in the exported pdf. In case you need to fill in a form where sections 4a and 4b should be filled in, please use the interactive pdf eAF until the issue has been solved.
Known issue	When exporting the pdf, the export is intermittently not triggered on the first attempt but might require multiple attempts before succeeding.
xEVMPD data 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 Workaround: use the interactive pdf eAF for variations where in section 4d option 'EU authorised representative option needs to be selected
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 limitation	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish

Known limitation	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 intermitted 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	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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	Present and Proposed section - implementation of the remaining features/functions. Expected deployment: Q3-Q4 2025
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Version: 1.2.0.5 (Release date 26/05/2025)

Version Goal: Alternative (OMS) company name improvement, MRP/DCP Procedure number for NAPs, UX/UI Design (Additional information)

Date: 26/05/2025

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 1.2.0.5	This release note is for the version 1.2.0.5 release go-live 26/05/2025

New stories released in this version

ID	Description	Comments
192586	UI Design – Additional info	The new UI design is implemented in the 'Additional information' section where information relating to Orphan medicinal procedures, Paediatrics and Market exclusivity is filled in where relevant. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.
248131	Alternative Organisation name - OMS	This is an improvement story to enable the user to remove the selected alternative organisation name
245681	MRP number field is now available for purely national products	It is now possible to add the MRP number for purely national products

Coming soon/we are currently working on

ID	Short description
UI Design	UI Design implementation to continue for the rest of the application and for the sections that were not finalised

Known Issues and Limitations

ID	Short description
Known issue	<p>A small number of products are affected by a synchronisation issue with PMS and the forms where they are used cannot be exported and finalised. Once added the products in the eAF, export the form and should you see the message ""Data refresh cannot be completed. Aborting the operation. Please retry again.", please use the interactive PDF instead. The teams are working on fixing this issue and a new message will be published once it is resolved.</p> <p>If you have already filled in the form and this issue occurs, please raise a ticket and the team might be able unblock the form.</p>
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Variations for ATC code should be done in the free text fields in Present and Proposed section
Known issue	The section 4a (Orphan) and 4b (paediatric) are not reflected correctly in the exported pdf. In case you need to fill in a form where sections 4a and 4b should be filled in, please use the interactive pdf eAF until the issue has been solved.
Known issue	When exporting the pdf, the export is intermittently not triggered on the first attempt but might require multiple attempts before succeeding.
xEVMPD data 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 Workaround: use the interactive pdf eAF for variations where in section 4d option 'EU authorised representative option needs to be selected
Known issue	<p>The selections from the Medical Device section 4d. are not correctly reflected in the pdf export in some cases.</p> <p>Please note: for variation applications indicating a change in the device in section 4d. please consider using the interactive pdf eAF.</p>
Known limitation	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish
Known limitation	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 intermitted 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	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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	Present and Proposed section - implementation of the remaining features/functions. Expected deployment: Q3-Q4 2025
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Version: 1.2.0.4 (Release date 13/05/2025)

Version Goal: Alternative (OMS) company name, UX/UI Design (Types of changes and Procedural information)

Date: 13/05/2025

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 1.2.0.4	This release note is for the version 1.2.0.4 release go-live 13/05/2025

New stories released in this version

ID	Description	Comments
192583	UI Design – Type(s) of change(s)	The new UI design is implemented in the 'Scope and procedure type' selection section. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.
192584	UI Design – Procedural information section	The new UI design is implemented in the 'Procedural information' section. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.
185709	Alternative Organisation name	The applicant is now able to select an alternative organisation name from OMS (where available) in addition to the 'OMS preferred organisation name'. The list of available Alternative names will be shown in the Procedural information section. Important: for the time being, once chosen, the "Alternative Company name" cannot be removed. An improvement will be implemented in future releases.
237371	PDF Paediatric Information section	If the Paediatric Information does not appear in "Additional information" section, then it will not be shown in the PDF either.
(bug) 244898	Signatory twice in the FHIR XML	A bug related to the signatory being shown twice in the FHIR XML was fixed

Coming soon/we are currently working on

ID	Short description
UI Design	UI Design implementation to continue for the rest of the application and for the sections that were not finalised

Known Issues and Limitations

ID	Short description
Known issue	A small number of products are affected by a synchronisation issue with PMS and the forms where they are used cannot be exported and finalised. Once added the products in the eAF, export the form and should you see the message ""Data refresh cannot be completed. Aborting the operation. Please retry again.", please use the interactive PDF instead. The teams are working on fixing this issue and a new message will be published once it is resolved.
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Variations for ATC code should be done in the free text fields in Present and Proposed section
Known issue	The section 4a (Orphan) and 4b (paediatric) are not reflected correctly in the exported pdf. In case you need to fill in a form where sections 4a and 4b should be filled in, please use the interactive pdf eAF until the issue has been solved.
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Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	Present and Proposed section - implementation of the remaining features/functions. Expected deployment: Q3-Q4 2025
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Version: 1.2.0.3 (Release date 28/04/2025)

Version Goal: MRP Procedure number

Date: 28/04/2025

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 1.2.0.3	This release note is for the version 1.2.0.3 release go-live 28/04/2025

New stories released in this version

ID	Description	Comments
215586	MRP Procedure number	Improvement on the validation rule for the MRP procedure number field: the error message is now triggered right after selecting the MRP/DCP products, and not just on the finalisation of the form

Coming soon/we are currently working on

ID	Short description
192583	Type(s) of change(s) section – UI design implementation. The new UI design will be implemented in the 'Scope and procedure type' selection section. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.
215586	Improvement to the validation rule for the MRP procedure number field - the error message will be triggered as a section level validation error (currently only as a finalisation error).
192584	Procedural information section – UI design implementation. The new UI design will be implemented in the 'Procedural information' section. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.

185709	Alternative Organisation name – the applicant will be able to select an alternative organisation name from OMS (where available) in addition to the 'OMS preferred organisation name'
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Known Issues and Limitations

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Known issue	A small number of products are affected by a synchronisation issue with PMS and the forms where they are used cannot be exported and finalised. Once added the products in the eAF, export the form and should you see the message ""Data refresh cannot be completed. Aborting the operation. Please retry again.", please use the interactive PDF instead. The teams are working on fixing this issue and a new message will be published once it is resolved.
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xEVMPD data 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 Workaround: use the interactive pdf eAF for variations where in section 4d option 'EU authorised representative option needs to be selected
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 limitation	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish

Known limitation	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 intermitted 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	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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	Present and Proposed section - implementation of the remaining features/functions. Expected deployment: Q3-Q4 2025
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Version: 1.2.0.2 (Release date 31/03/2025)

Version Goal: Select product UI design

Date: 31/03/2025

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 1.2.0.2	This release note is for the version 1.2.0.2 release go-live 31/03/2025

New stories released in this version

ID	Description	Comments
192582	Product selection - UI design implementation	The new UI design has been implemented in the 'Product selection' section. This is part 1 of the implementation containing only visual changes and further functional improvements to this section will be delivered in a later stage.
239877	PDF Document properties	The "Application" property of the exported PDF now contains "PLM Generator", the Author now contains "European Medicines Agency"

Coming soon/we are currently working on

ID	Short description
192583	Type(s) of change(s) section – UI design implementation. The new UI design will be implemented in the 'Scope and procedure type' selection section. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.
215586	Improvement to the validation rule for the MRP procedure number field - the error message will be triggered as a section level validation error (currently only as a finalisation error).
192584	Procedural information section – UI design implementation. The new UI design will be implemented in the 'Procedural information' section. This is part 1 of the

	implementation and further changes and improvements to this section will be delivered in a later stage.
185709	Alternative Organisation name – the applicant will be able to select an alternative organisation name from OMS (where available) in addition to the 'OMS preferred organisation name'

Known Issues and Limitations

ID	Short description
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Variations for ATC code should be done in the free text fields in Present and Proposed section
Known issue	The section 4a (Orphan) and 4b (paediatric) are not reflected correctly in the exported pdf. In case you need to fill in a form where sections 4a and 4b should be filled in, please use the interactive pdf eAF until the issue has been solved.
Known issue	When exporting the pdf, the export is intermittently not triggered on the first attempt but might require multiple attempts before succeeding.
xEVMPD data 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 Workaround: use the interactive pdf eAF for variations where in section 4d option 'EU authorised representative option needs to be selected
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 limitation	Products authorised in Finland: The full name of product is displayed (randomly) either in Finnish or Swedish
Known limitation	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 intermitted 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	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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	Present and Proposed section - implementation of the remaining features/functions. Expected deployment: Q3-Q4 2025
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Version: 1.2.0.1 (Release date 17/03/2025)

Version Goal: Create new application UI design, Bug fixes

Date: 17/03/2025

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 1.2.0.1	This release note is for the version 1.2.0.1 release go-live 17/03/2025

New stories released in this version

ID	Description	Comments
192581	Create new application - UI design implementation	The new UI design has been implemented in the 'Create new application' section. This is part 1 of the implementation and further changes to this section will be delivered in a later stage.
235142	The coordinator list is empty on application	The coordinator list is empty when viewed from the list of applications. The issue has been fixed and the co-authors are now correctly displayed

Coming soon/we are currently working on

ID	Short description
192582	Product selection – UI design implementation. The new UI design will be implemented in the 'Product selection' section. This is part 1 of the implementation and further changes and improvements to this section will be delivered in a later stage.

Known Issues and Limitations

ID	Short description
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Variations

	for ATC code should be done in the free text fields in Present and Proposed section
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.
xEVMPD data 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 Workaround: use the interactive pdf eAF for variations where in section 4d option 'EU authorised representative option needs to be selected
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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	Present and Proposed section - implementation of the remaining features/functions. Expected deployment: Q3-Q4 2025
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Version: 1.2.0.0 (Release date 06/03/2025)

Version Goal: Integrity Stamp, Proof of payment improvements

Date: 06/03/2025

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 1.2.0.0	This release note is for the version 1.2.0.0 release go-live 06/03/2025

New stories released in this version

ID	Description	Comments
219351	Integrity Stamp	<p>The integrity stamp was deployed to production.</p> <ul style="list-style-type: none">• Upon 'Finalisation', the PLM Portal web based human variation eAF will be locked and moved to the 'Completed' tab (the form can be opened for further editing if necessary)• The form will be locked with a digital 'signature' called eAF integrity warranty (or eAF integrity stamp), containing the date of the signature• After 6th of March the system will include the stamp on all forms that are finalised• Forms that have not been finalised (i.e. do not contain the integrity stamp) will be rejected by the regulators in the future – date to be confirmed!• The applicants will still be able to include additional digital signature(s) into the finalised form (exported pdf)• It will not be possible to include an image of a signature or an 'adobe signature' to the form after the stamp is included

		<ul style="list-style-type: none"> There is no integrity stamp in the 'legacy' interactive pdf eAFs
233025 234197	Proof of payment improvements	The experience of the user with the proof of payment section was improved by separating the Yes/No options for the proof of payment and by applying several performance enhancements

Coming soon/we are currently working on

ID	Short description
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	Present and Proposed section re-design and performance improvements implementation of the remaining features/functions. 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
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Any changes in the ATC code must be done in the standard Present and Proposed boxes
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 Workaround: use the interactive pdf eAF for variations where section 4d needs to be filled in

Known issue	<p>The selections from the Medical Device section 4d. are not correctly reflected in the pdf export in some cases.</p> <p>Please note: for variation applications indicating a change in the device in section 4d. please consider using the interactive pdf eAF.</p>
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	<p>23545 - Performance issues</p> <p>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.</p>
Known limitation	23963 - Finalisation: Annexed document and Declaration Section are presented in random order

Version: 1.1.1.4 (Release date 18/02/2025)

Version Goal: Proof of payment improvements, Product selection improvement, Bug fixes

Date: 18/02/2025

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 1.1.1.4	This release note is for the version 1.1.1.4 release go-live 18/02/2025

New stories released in this version

ID	Description	Comments
226938	Product selection: search product number of rows	In the product selection page, the number of rows can not be changed to 500 entries. Other minor improvements were implemented on this page
226666	Proposed changes	Improvements were implemented for the auto-save of the information added in the present-proposed and a prompt to ask the user if the changes should be saved
233162	Procedural information	The member state in the contact person window is now mandatory
231898	Finalisation	A bug related to the printing twice of the additional signatory was fixed
229986	NCA access – Authorisation status	In the View available products window, the NCA users can now see the authorisation status
229531	Procedural information – Contact person	A bug related to adding maximum one contact person for a form with CAPs only was fixed
234220	Finalisation – Proof of payment	Fixes were made in the Proof of Payment section related to the appearance in various scenarios of the Member states
234062	Bug fix - Additional Information: RO Form shows section failed after submission	A bug related to the "Additional information" section appearing only after finalising the form and marked as "Incomplete" (the form becomes "RO" (Read-Only)) was fixed

Coming soon/we are currently working on

ID	Short description
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	<p>Present and Proposed section re-design and performance improvements implementation of the remaining features/functions.</p> <p>Expected deployment: Q1 2025</p>
219351 Development finalised – pending production deployment	<p>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.</p> <p>Important note: The integrity stamp is a digital signature which is placed in the pdf export automatically by the system when the application form is Finalised.</p> <p>It is planned that once this feature is rolled out, it will become mandatory to 'Finalise' the forms meaning that if an eAF is submitted without the stamp it is likely to lead to rejection of the form and request to resubmit with a 'Finalised' form.</p> <p>Please note that it is possible to include an additional, company specific 'Digital signature' in the exported, Finalised eAF pdf form after the automated system integrity stamp has been added. Other types of signatures, such as image of a signature and adobe signature cannot be included in the form after the integrity stamp has been added by the system.</p> <p>Expected deployment: Q1 2025</p>
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Known Issues and Limitations

ID	Short description
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Any changes in the ATC code must be done in the standard Present and Proposed boxes
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 Workaround: use the interactive pdf eAF for variations where section 4d needs to be filled in
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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order

Version: 1.1.1.3 (Release date 03/02/2025)

Version Goal: Proof of payment

Date: 03/02/2025

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 1.1.1.3	This release note is for the version 1.1.1.3 release go-live 03/02/2025

New stories released in this version

ID	Description	Comments
207009	Proof of Payment section: business rules fixes and non-CAP procedure support It is now possible to indicate different payment details for variations for countries with pre-payment and countries with billing details	For CAP only variations where procedure type is Type I, the proof of payment section is now hidden. For EMA led mixed CAP/MRP/DCP application, it is now possible to indicate payment details for the relevant member states. Please note that the value European Union should not be selected for Type I variations. Known issues/limitations: Variations containing products authorised through National authorisation (NP) and with a mix of CAPs and NP products, it is currently not possible to use the form.
228315	Declaration section: Hide the parallel procedures product grid in all possible scenarios	The grid where the details of the product(s) and procedure(s) is no longer required and has been removed for all procedures.
229531	Procedural information: Contact for applications with CAPs	A bug related to the contact person for CAPs was fixed (only one contact person can be added for the EU)
230961	Proposed Changes: Create/Edit modal should display Filter, not a search	In the proposed changes, the filter box now shows "Filter" instead of "Search"

Coming soon/we are currently working on

ID	Short description
Important note to all PLM Portal users	<p>Due to an identified issue with ingredient data on the PLM Portal, the following medicinal product were removed from the Product Lifecycle Management Portal from 13 to 17 January 2025: all ingredients and their strengths, Pharmaceutical products and routes of administration, Package Items, Package Item Materials, Package Manufactured Items, ATC codes.</p> <p>From 20 January 2025, the removed data was re-uploaded in phases and all Centrally Authorised Products' (CAPs) data and non-CAPs is now available.</p>
Various	Performance improvements e.g. Finalisation section – implementation postponed
210325	<p>Present and Proposed section re-design and performance improvements implementation of the remaining features/functions.</p> <p>Expected deployment: Q1 2025</p>
219351 Development finalised – pending production deployment	<p>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.</p> <p>Important note: The integrity stamp is a digital signature which is placed in the pdf export automatically by the system when the application form is Finalised.</p> <p>It is planned that once this feature is rolled out, it will become mandatory to 'Finalise' the forms meaning that if an eAF is submitted without the stamp it is likely to lead to rejection of the form and request to resubmit with a 'Finalised' form.</p> <p>Please note that it is possible to include an additional, company specific 'Digital signature' in the exported, Finalised eAF pdf form after the automated system integrity stamp has been added. Other types of signatures, such as image of a signature and adobe signature cannot be included in the form after the integrity stamp has been added by the system.</p> <p>Expected deployment: Q1 2025</p>
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Known Issues and Limitations

ID	Short description
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Any changes in the ATC code must be done in the standard Present and Proposed boxes

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 Workaround: use the interactive pdf eAF for variations where section 4d needs to be filled in
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 <u>variation classification guideline</u>
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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order
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Version: 1.1.1.2 (Release date 20/01/2025)

Version Goal: Updated present and proposed section

Date: 20/01/2025

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 1.1.1.2	This release note is for the version 1.1.1.2 release go-live 20/01/2025

New stories released in this version

ID	Description	Comments
228208 230244 230245 230256 230754	Present and proposed improvements/bug fixes	Improvements and bugs in the Present and Proposed section were deployed: <ul style="list-style-type: none">• User not able to Save proposed changes without adding new section• Duplicate packages are appearing for existing records on deleting and re-adding the same product• Duplicate packages are appearing in existing proposed changes record on adding new product• After adding Procedure number the page is not responsive and getting error in console

Coming soon/we are currently working on

ID	Short description
Important note to all PLM Portal users	Due to an identified issue with ingredient data on the PLM Portal, the following medicinal product data will be removed from the Product Lifecycle Management Portal from 13 to 17 January 2025: <ul style="list-style-type: none">• All ingredients and their strengths• Pharmaceutical products and routes of administration

	<ul style="list-style-type: none"> • Package Items, Package Item Materials, Package Manufactured Items • ATC codes <p><i>This means the above data will be unavailable in Product Management Service Product User Interface and Human Variations electronic Application Form.</i></p> <p><i>In practice, for PLM Portal web-based eAF users this means that fields containing this information will be empty in the eAFs generated from the PLM Portal during this period. The missing data is not expected to impact the users of the eAF for variations for Centrally Authorised Products; and eAFs submitted with empty fields where the data is 'missing' due to the data cleansing exercise will not be rejected. We kindly request you not to report missing data/data issues in the eAF via the EMA Service desk during this period.</i></p> <p><i>This means that PLM Portal eAF users should be able to continue to use the web-based form during this period unless unexpected issues, that were not found during testing, are found once the data cleansing process starts. However, users should note that the interactive pdf eAF is available for use for all variation procedures and applicants may feel more comfortable using the pdf eAF.</i></p> <p>From 20 January 2025, the removed data will be re-uploaded in phases:</p> <ul style="list-style-type: none"> • All Centrally Authorised Products' (CAPs) data will be available from 20 January 2025; • Non-CAPs data will gradually reappear over the following two weeks.
Various	Performance improvements e.g. Finalisation section – implementation postponed
207009	<p>Proof of Payment section: business rules fixes and non-CAP procedure support</p> <p>It is currently not possible to indicate different details for non-CAP WS variations for countries with pre-payment and countries with billing details</p> <p>Expected deployment: Q1 2025</p>
210325	<p>Present and Proposed section re-design and performance improvements implementation of the remaining features/functions.</p> <p>Expected deployment: Q1 2025</p>
219351 Development finalised – pending production deployment	<p>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.</p> <p>Important note: The integrity stamp is a digital signature which is placed in the pdf export automatically by the system when the application form is Finalised.</p> <p>It is planned that once this feature is rolled out, it will become mandatory to 'Finalise' the forms meaning that if an eAF is submitted without the stamp it is likely to lead to rejection of the form and request to resubmit with a 'Finalised' form.</p>

	<p>Please note that it is possible to include an additional, company specific 'Digital signature' in the exported, Finalised eAF pdf form after the automated system integrity stamp has been added. Other types of signatures, such as image of a signature and adobe signature cannot be included in the form after the integrity stamp has been added by the system.</p> <p>Expected deployment: Q1 2025</p>
Various	Analysis of the next set of structured changes e.g. ATC code, Medical Device

Known Issues and Limitations

ID	Short description
230186	The ATC code added in the Present and Proposed using the ATC code popup is not completely functional, and the display in the PDF is not correct. Any changes in the ATC code must be done in the standard Present and Proposed boxes
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 Workaround: use the interactive pdf eAF for variations where section 4d needs to be filled in
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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order

Version: 1.1.1.1 (Release date 07/01/2025)

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

Date: 07/01/2025

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 1.1.1.1	This release note is for the version 1.1.1.1 release go-live 07/01/2025

New stories released in this version

ID	Description	Comments
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227233	Export: User cannot export and gets error 'Data refresh cannot be completed'	<p>A bug related to pdf export has been fixed.</p> <p>Please note that if you experience issues with 'Export' function, please try to repeat the 'Export'. It is possible that up to 3 or 4 attempts are needed before the export is triggered in some cases.</p>
228697	Procedural Information: User not able to save the 'Application form Contact person' details	<p>A bug related to saving application form contact person has been fixed. It is now possible to add and save the contact person details in the form.</p> <p>Known issue: Due to a bug the system allows users to add multiple contact persons for applications containing CAPs however, the validation rule preventing adding multiple contact persons is in place, but not visible. If you are getting a persistent error when 'Finalising' the form and the error points to Procedural Information section, please ensure that you have included only 1 application contact person for applications containing at least 1 Centrally Authorised Product.</p>
<p>Bugs:</p> <p>227076</p> <p>225964</p> <p>226673</p> <p>223452</p>	Present and Proposed section – Implement new functionality	<p>Partial implementation of the improved Present and Proposed section with new User Interface (UX) designs. This is fixing the known issue/bug:</p> <ul style="list-style-type: none"> • Select product packages for proposed changes sub window: the filtering is limited (227076) • View button on scopes is without functionality: the view button has now been hidden to avoid confusion of non-functioning button (225964) • List of Packaged medicinal products not loading: issue with loading packaged medicinal products in the product packages window was fixed • Packages to take a long time to load (the time it takes to display the packages in the product packages window has been reduced)

<p>226154</p> <p>(to address bugs implemented in: 210325)</p>		<ul style="list-style-type: none"> Medicinal Product PMS ID was missing in the product packages window <p>Remaining known issues and bugs:</p> <ul style="list-style-type: none"> when filters are used top level selection of medicinal products and/or packaged medicinal products 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 <i>Previous, Next, Copy, Separate</i> and <i>Outline</i> 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 It is not possible to view the scope details in the Package and Scope window
<p>229512</p>	<p>Finalisation: PDF – the text included in the Notes box is not displayed in the exported pdf</p>	<p>The text included in the Notes field in the parallel procedures section is now displayed in the pdf export of the eAF</p>

226690	Finalisation: Parallel variations section label updated	The section header (label) has been updated to reflect the business requirement: Declaration of the application about the submission(s) of the same variation (or group of variations) in other Member States / EMA
224122	Product selection: only 5 product fields are shown in View selected products view	A bug in the table displaying selected products has been fixed and all selected products are now displayed (pagination available where list exceeds number of rows on the page)
205988	Product selection: the product search is not working properly (filter for authorised dose form)	A bug in the product selection with filter 'authorised dose form' has been fixed

Coming soon/we are currently working on

ID	Short description
Important note to all PLM Portal users	<p>Due to an identified issue with ingredient data on the PLM Portal, the following medicinal product data will be removed from the Product Lifecycle Management Portal from 13 to 17 January 2025:</p> <ul style="list-style-type: none"> • All ingredients and their strengths • Pharmaceutical products and routes of administration • Package Items, Package Item Materials, Package Manufactured Items • ATC codes <p><i>This means the above data will be unavailable in Product Management Service Product User Interface and Human Variations electronic Application Form.</i></p> <p><i>In practice, for PLM Portal web-based eAF users this means that fields containing this information will be empty in the eAFs generated from the PLM Portal during this period. The missing data is not expected to impact the users of the eAF for variations for Centrally Authorised Products; and eAFs submitted with empty fields where the data is 'missing' due to the data cleansing exercise will not be rejected. We kindly request you not to report missing data/data issues in the eAF via the EMA Service desk during this period.</i></p> <p><i>This means that PLM Portal eAF users should be able to continue to use the web-based form during this period unless unexpected issues, that were not found during testing, are found once the data cleansing process starts. However, users should note that the interactive pdf eAF is available for use for all variation procedures and applicants may feel more comfortable using the pdf eAF.</i></p> <p>From 20 January 2025, the removed data will be re-uploaded in phases:</p>

	<ul style="list-style-type: none"> All Centrally Authorised Products' (CAPs) data will be available from 20 January 2025; Non-CAPs data will gradually reappear over the following two weeks.
Various	Performance improvements e.g. Finalisation section – implementation postponed
207009	<p>Proof of Payment section: business rules fixes and non-CAP procedure support</p> <p>It is currently not possible to indicate different details for non-CAP WS variations for countries with pre-payment and countries with billing details</p> <p>Expected deployment: Q1 2025</p>
210325	<p>Present and Proposed section re-design and performance improvements implementation of the remaining features/functions.</p> <p>Expected deployment: Q1 2025</p>
219351 Development finalised – pending production deployment	<p>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.</p> <p>Important note: The integrity stamp is a digital signature which is placed in the pdf export automatically by the system when the application form is Finalised.</p> <p>It is planned that once this feature is rolled out, it will become mandatory to 'Finalise' the forms meaning that if an eAF is submitted without the stamp it is likely to lead to rejection of the form and request to resubmit with a 'Finalised' form.</p> <p>Please note that it is possible to include an additional, company specific 'Digital signature' in the exported, Finalised eAF pdf form after the automated system integrity stamp has been added. Other types of signatures, such as image of a signature and adobe signature cannot be included in the form after the integrity stamp has been added by the system.</p> <p>Expected deployment: Q1 2025</p>
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)
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 Workaround: use the interactive pdf eAF for variations where section 4d needs to be filled in
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	23963 - Finalisation: Annexed document and Declaration Section are presented in random order

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/worksharing/super-grouping
210325	Present and Proposed section – Implement new functionality	<p>Partial implementation of the improved Present and Proposed section with new User Interface (UX) designs</p> <p>Known issues and bugs:</p> <ul style="list-style-type: none">• 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

		<p>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</p> <ul style="list-style-type: none"> • Saving closes the present and proposed windows and takes the user back to the Proposed Changes home page • <i>Previous, Next, Copy, Separate</i> and <i>Outline</i> 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)	<p>The business rules have been updated and the Declaration on parallel variations has been updated.</p> <p>Note:</p> <ul style="list-style-type: none"> • 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	<p>The selections from the Medical Device section 4d. are not correctly reflected in the pdf export in some cases.</p> <p>Please note: for variation applications indicating a change in the device in section 4d. please consider using the interactive pdf eAF.</p>
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	<p>23545 - Performance issues</p> <p>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.</p>
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 is 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 is 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
Intermittent 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 is 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
Intermittent 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 from 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: 28 th 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
Intermittent 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
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Known limitation	Human Variations eAF	The system creates an empty row in summary of Present and Proposed when 'save' is pressed after filling in certain sections. The empty row should be edited to contain the changes or deleted
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
Intermittent 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: <ul style="list-style-type: none">• Procedural information• Left navigation menu• View eAF list• Create new eAF
134341	Bug - Validation error "The field EMA procedure number/Competent Authority is required."	In the additional details, for "Type IB and Type II variations - Paediatric Requirements", the validation error "The field EMA procedure number/Competent Authority is required." does no longer appear upon saving the page.

189849	Bug - Ordering of Products on Product Selection	The display of the products on Product selection section is again based on alphabetical order.
189854	Bug – packages	Packages are now loading faster under Product selection and Present/Proposed section
197043	Bug – View selected products	In the “View selected products”, now all selected products are shown
199677	Bug – Signatory date	In the main and additional signatory, the date remains as selected by the user

Coming soon/we are currently working on

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

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
Intermittent 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
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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
Intermittent 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
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*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
Intermittent 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
Intermittent 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
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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	Intermittent 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
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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
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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: <ul style="list-style-type: none">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	<p>medicinal products should now be visible in the Proposed changes section.</p> <p>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.</p>
76861	Select All in combination with pagination will delete the previous selection	<p>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</p> <p>NOTE: There is a known issue affecting this section and only approx. 200 packages can be selected at one time.</p>
77891	Update the Validation Status of Procedural Information Section	<p>Any field validation change should update the validation status.</p> <p>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.</p>
86890	Packages may not be loaded in when present/proposed is opened	<p>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.</p>
93686	Friendly name validates at 100 chars but fails at 80 chars already	<p>A technical issue (bug) detected on the background preventing finalisation of the eAF with a Friendly name exceeding 80 characters has been fixed.</p>
94280	MAH phone number should validate without save	<p>The validation error is no longer displayed when the 'validate' button is pressed after including the MAH phone number.</p>
95272	Procedural Information - Reference Member State field error	<p>Only relevant to WS procedures that do not contain any CAPs (fixed in preparation for NAPs release):</p> <ul style="list-style-type: none"> The error message on RMS now has its own line

		<ul style="list-style-type: none"> There is a red border around the RMS field if no country has been selected as the RMS.
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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
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26157	Human Variations eAF	Packages missing in UAT which are in Production
26203	Human Variations eAF	Number of selected packages are not updated correctly
23910	Human Variations eAF	Inconsistent button behaviour by viewing 'selected packaged medicinal product(s)'
16209	Human Variations eAF	Symbol "?" is displaying in font style drop down
22733	Human Variations eAF	Error for product and scope selection, package check box is disabled
22845	PLM Portal	Deletion of Application Form is not working
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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
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23961	PLM Portal	Drop-down invisible in Application Forms overview
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23963	Human Variations eAF	Finalisation: Statement in Annexed document and Declaration Section in random order in DADI
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23967	Human Variations eAF	Finalisation section - Proof of payment - able to select either Yes or NO

23968	Human Variations eAF	Hyphenations are incorrect in tab type of changes, in the view scope and description and in the view conditions and documentation section
23971	Human Variations eAF	Proposal for Organisation Details – Split Text
23974	Human Variations eAF	Suggestion - Scope section - Information is not displayed in a user-friendly manner.
24006	PLM Portal	Refresh button producing error on Application list view
24907	Human Variations eAF	Select all checkbox does not "Select All" in "Proposed Changes" section
25269	Human Variations eAF	Product select screen shows 0/0 product presentation
25301	Human Variations eAF	Precise scope and background for information section not saved
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

Version: 1.0.1.7 (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
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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
25301	Human Variations eAF	Precise scope and background for information section not saved
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

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

Version Goal: PLM Portal bug fix release

Date: 21/02/2023

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.1.6	This release note is for the BUGFIX version 1.0.1.6 release go-live 21/02/2023
Update of the human readable pdf export	PDF version 2.0.5.1	This release note is for the BUGFIX version 2.0.5.1 release go-live 20/02/2023

Update of the human readable pdf export	PDF Version 2.0.2.2* *Please note that the newly introduced 4 th 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: <ul style="list-style-type: none"> • 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	<p>Present and Proposed section:</p> <ul style="list-style-type: none"> • 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 	<p>Input fields for the ASMF number and DUNS number have been added to the web UI of eAF.</p> <p>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.</p> <p>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.</p>

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	<p>PDF Version 2.0.2.2*</p> <p>*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.</p>	<p>This release note is for the BUGFIX version 2.0.2 release go-live 23/01/2023</p>
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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 14 th October 2022. The text now reads 'I declare this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder. This update was done to ensure the correct use of the section – for any change that concerns an organisation e.g. change of a manufacturing site, the site must be selected from OMS. For further details on the use of this section please see: European Medicines Agency practical guidance on

		the application form for centralised type IA and IB variations page 13
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
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23912	Human Variations eAF	Menu handling checkbox - Additional information does not disappear where it should have

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23915	Human Variations eAF	Organisation information - parent organisation label does not match
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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
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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 ones in the FHIR Message (XML)	Although the selected Medicinal Products were taken into account in the PDF, the packaged products weren't listed correctly. This fix is visible in the PDF version 2.0.2. There is no change to FHIR version.
23407 – web eAF	Text is cut into two halves and displaying below	In the procedural information section the text 'annual variation for human influenza vaccines' was cut in the middle of the word influenza.

Known Issues

ID	Component	Short description
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.
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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
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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
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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
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23923	Human Variations eAF	Drop down list member state country doesn't open - intermittent
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23961	PLM Portal	Drop-down invisible in Application Forms overview
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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
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25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
24731	Human Variations eAF	The Proposed Package Item Content is not linked to Application Form

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

Version Goal: Go-Live PLM Portal

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

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.1.1	This release note is for the BUGFIX version 1.0.1.1 release go-live 14/11/2022
Implementation of the human readable pdf export	PDF Version 2.0.1	This release note is for the BUGFIX version 2.0.1 release go-live 17/11/2022
Implementation of the FHIR xml	FHIR XML 1.0.2.0	This release note is for the BUGFIX version 1.0.2.0 release go-live 16/11/2022

Issues fixed in this version

ID	Description	Comments
24816 – web eAF	RPI cannot be blank validation message is displaying always when CAP product is selected	Remaining known issue: Validation error in product selection is incorrectly showing up if 'Validation' is pressed immediately after Saving. This issue has been partly fixed; the incorrect list was linked to the products resulting RPI validation issue for every product. This part of the issue has been addressed.
24731 – web eAF	The Proposed Package Item Content is not linked to Application Form	The Proposed Package Item Content created when Present Package Item Content doesn't exist and has no link to Application Form and Application Form Type. Hence these records are not available for FHIR XML creation and doesn't reach PDF.
24728 – web eAF	Update Chatbot look and feel	

24649 – web eAF	Additional information section is displaying as completed without validate/export	Additional information section was automatically changed to 'completed' status when it was not filled in/validated by the user. After the bugfix the additional information section remains in 'not completed' state until the user manually validates the section
24819 – web eAF	PDF export is taking long time and loading is displaying for long time	This issue was affecting forms where there were more than 10 medicinal products selected.
24991 – web eAF	Medical device is displaying proposed changes without click on save	Medical device section was displayed even when the user clicked 'cancel' button and no changes were made and no save button was pressed.
24703 – web eAF	Incorrect date sorting for Export window	The list of pdf exports was displayed in random order.
24805 – web eAF	Prompt message on 'Delete device'	Issue relating to 'Delete device' button has been fixed.
24924 – web eAF	Validation button is not working in all sections	Validate button was not working correctly in all sections.
24990 – web eAF	Validation error message is displayed in proposed changes section after combining scopes and packaged medicinal products	Scrambled validation error message is not be shown when scope and product combinations are updated.
26295 – FHIR XML	The HTML Change Provenance (unstructured provenance) doesn't contain the HTML changes when the proposed value and the present value are the same	This issue resulted a missing present and proposed section in the FHIR XML and in the pdf export when same value was presented in both 'present' and 'proposed' fields e.g. if user had added 'see details on separate annex' in both fields, the present and proposed sections were not available in the xml and were hidden in the pdf.
26247 – FHIR XML	Impossible to use the same image twice in the text areas in a form	
22013 - pdf	Updated text for the 'no address change' in the declaration in present and proposed section	The text has been aligned to correspond with the updated text as per pdf eAF release on 14 th October 2022. The text now reads 'I declare this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder. This update was done to ensure the correct use of the section

		<p>– 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</p>
24738 – pdf	<ul style="list-style-type: none"> Removed APPENDIX section Structured changes are shown in section 3 Text in HTML fields is same size as all the PDF 	<p>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.</p> <p>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.</p>

Known Issues

ID	Component	Short description
27565	Human Variations eAF	<p>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.</p> <p>Note: This does not result in business validation error as this is a known bug in the form.</p>
Known limitation	PLM Portal	Copy application feature not available yet
Known limitation	Human Variations eAF	Cannot select 'includes line extension' when single scope added
Known limitation	Human Variations eAF	It is not possible to change the 'Friendly name'
Known limitation	Human Variations eAF	Form cannot be used for variations that add new presentation
Known limitation	Human Variations eAF	Delay in display of packaged medicinal products in product selection.
Known limitation	Human Variations eAF	Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional Information section
Known limitation	Human Variations eAF	Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope)

Known limitation	FHIR xml	Commercially Confidential Data not related to the application content/variation present in the FHIR XML
Known limitation	Human Variations eAF	The system creates an empty row in summary of Present and Proposed when 'save' is pressed after filling in certain sections. The empty row should be edited to contain the changes or deleted
Known limitation	Human Variations eAF	Other Applications – Select EMA Procedure has no related procedures available for selection. Workaround: use the +Add to manually add other ongoing applications
Known limitation	Human Variations eAF	Present and Proposed section: ASMF number and DUNS number fields missing from the Web UI. If these need to be provided, please use Precise Scope section or the interactive pdf eAF.
25395	Human Variations eAF	Some inactive organisations from OMS available in Contact Person organisation section
25396	Human Variations eAF	Packaged medicinal products are not shown when combining scopes and medicinal products
25400	Human Variations eAF	Incorrect calculation of number of selected scopes in the summary page
23910	Human Variations eAF	eAF allows only two signatories
23910	Human Variations eAF	Inconsistent button behavior by viewing 'selected packaged medicinal product(s)'
16209	Human Variations eAF	Symbol "?" is displaying in font style drop down
22733	Human Variations eAF	Error for product and scope selection, package check box is disabled
22845	PLM Portal	Deletion of Application Form is not working – Using 'delete application form' in the deactivated folder results the deactivated form being moved back to 'Drafts'
23545	PLM Portal	Performance issues
23849	Human Variations eAF	Annexed Documents Section: External links in the help text referring to notice to applicant cannot be selected easily
23851	Human Variations eAF	Search on present-proposed disappearing
23896	Human Variations eAF	Error after wrong date format for Implementation date

23912	Human Variations eAF	Menu handling checkbox - Additional information does not disappear where it should have
23913	Human Variations eAF	Precise Scope & Background Info Pop-Up
23915	Human Variations eAF	Organisation information - parent organisation label does not match
23923	Human Variations eAF	Drop down list member state country doesn't open - intermittent
23931	Human Variations eAF	Double-clicking Save button for Change(s) Scope creates duplicates
23961	PLM Portal	Drop-down invisible in Application Forms overview
23963	Human Variations eAF	Changes Implementation Date issue
23963	Human Variations eAF	Finalisation: Statement in Annexed document and Declaration Section in random order in DADI
23965	Human Variations eAF	Conditions and documentation in DADI are not in the same order as in the variation classification guideline
23966	Human Variations eAF	Not possible to paste an image to the Present and Proposed fields in the Present and Proposed Value(s) tab
23967	Human Variations eAF	Finalisation section - Proof of payment - able to select either Yes or NO
23968	Human Variations eAF	Hyphenations are incorrect in tab type of changes, in the view scope and description and in the view conditions and documentation section
23969	Human Variations eAF	Cannot select more than one organisation in Proposed Organisation field
23971	Human Variations eAF	Proposal for Organisation Details – Split Text
23974	Human Variations eAF	Suggestion - Scope section - Information is not displayed in a user-friendly manner.
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Version: 1.0.0.0 (Release date 04/11/2022)

Version Goal: Go-Live PLM Portal

Date: 04/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

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

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