



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 November 2023

PLM Portal eAF - Release Notes

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

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

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

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

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

The most recent release appears first.

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About this Document

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

The most recent release appears first.

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

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

For additional information on the PLM portal see this:

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

Version: 1.0.1.12 (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 | Improve communication – 'news' tile on homepage |

| | | |
|-------|-------------------------|---------------------------------------------------------------------------------------------|
| | eAF | |
| 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 | Error for product and scope selection, package check box is |

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|-------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| | eAF | 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 |
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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 |
| 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 | It is not possible to change the 'Friendly name' |

| | | |
|-------|-------------------------|-----------------------------------------------------------------------------------------------------------------|
| | eAF | |
| 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 |

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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 |
| 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 combining scopes and | 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 |

| | | |
|-------|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | medicinal products | <p>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 • There is a red border around the RMS field if no country has been selected as the RMS. |

Coming soon/we are currently working on

| ID | Component | Short description |
|-------|----------------------|-----------------------------------------------------------------------------------------------------------------|
| 11086 | PLM Portal | Copy application feature not available yet |
| 246 | Human Variations eAF | It is not possible to change the 'Friendly name' |
| 25715 | Human Variations eAF | Form cannot be used for variations that add new presentation |
| 37644 | Human Variations eAF | Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope) |
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Known Issues

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|------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Known limitation | Human Variations eAF | Delay in display of packaged medicinal products in product selection. |
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| 25395 | Human Variations | Some inactive organisations from OMS available in Contact |

| | | |
|-------|----------------------|-----------------------------------------------------------------------------------------------------------------------|
| | eAF | 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 |
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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. |
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| 16208 | Human Variations eAF | Select All button must select all the available records in Available Products table and Packaged Products table |
| 11086 | PLM Portal | Copy application feature not available yet |
| 246 | Human Variations eAF | It is not possible to change the 'Friendly name' |
| 25715 | Human Variations eAF | Form cannot be used for variations that add new presentation |

| | | |
|------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Known limitation | Human Variations eAF | Delay in display of packaged medicinal products in product selection. |
| Known limitation | Human Variations eAF | Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional Information section |
| 37644 | Human Variations eAF | Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope) |
| 38300 | FHIR xml | Commercially Confidential Data not related to the application content/variation present in the FHIR XML |
| Known limitation | Human Variations eAF | The system creates an empty row in summary of Present and Proposed when 'save' is pressed after filling in certain sections. The empty row should be edited to contain the changes or deleted |
| Known limitation | Human Variations eAF | Other Applications – Select EMA Procedure has no related procedures available for selection/has only limited procedures available for some products. Workaround: use the +Add to manually add other ongoing applications |
| 23547 | Human Variations eAF | Procedural information: Some mandatory fields are not mandatory in the form |
| 25395 | Human Variations eAF | Some inactive organisations from OMS available in Contact Person organisation section |
| 25400 | Human Variations eAF | Incorrect calculation of number of selected scopes in the summary page |
| 15504 | Human Variations eAF | Deleted product package details are still appearing in Proposed changes section |
| 29109 | Human Variations eAF | Improve communication – 'news' tile on homepage |
| 29121 | Human Variations eAF | Improve communication – guidance and support page |
| 35130 | Human Variations eAF | Improve communication – change guidance documentation on login page from IRIS to PLM Portal |
| 26157 | Human Variations eAF | Packages missing in UAT which are in Production |
| 26203 | Human Variations eAF | Number of selected packages are not updated correctly |
| 23910 | Human Variations | Inconsistent button behaviour by viewing 'selected packaged |

| | | |
|-------|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| | eAF | 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 | Suggestion - Scope section - Information is not displayed in a |

| | | |
|------------------|---------------------------------|---------------------------------------------------------------------------------------------------|
| | eAF | user-friendly manner. |
| 24006 | PLM Portal | Refresh button producing error on Application list view |
| 24907 | Human Variations eAF | Select all checkbox does not "Select All" in "Proposed Changes" section |
| 25269 | Human Variations eAF | Product select screen shows 0/0 product presentation |
| 25301 | Human Variations eAF | Precise scope and background for information section not saved |
| 25395 | Human Variations eAF | Some inactive organisations from OMS available in Contact Person organisation section |
| 25396 | Human Variations eAF | Packaged medicinal products are not shown when combining scopes and medicinal products |
| 24731 | Human Variations eAF | The Proposed Package Item Content is not linked to Application Form |

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

Version Goal: PLM Portal bug fix release

Date: 17/04/2023

Environment: production

Version content (testable functionalities/use cases)

Version content

| Functionality/use case | Component | Short description |
|------------------------------------------------------------------|--------------------------------------|--------------------------------------------------------------------------------|
| Implementation of the web based human variation application form | Human Variations eAF Version 1.0.1.7 | This release note is for the BUGFIX version 1.0.1.7 release go-live 17/04/2023 |
| Update of the human readable pdf export | PDF version 2.0.5.1 | This release note is for the BUGFIX version 2.0.5.1 release go-live 20/02/2023 |
| Implementation of the FHIR | FHIR XML | |

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|-----|---------|--|
| 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 |

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| 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 |

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| 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) |

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| | | <ul style="list-style-type: none"> • Ingredient/Ingredient Strength/Ingredient Documentation FHIR refactoring (30382/30383/30387) • Attach every DeviceDefinition to a Medicinal Product (38537) • Add the Source ID to the ATC while keeping the ATC name as well (38779) • Minor fixes to the Device variation as new edge-cases were tested (37124/38274) |
|--|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Issues fixed in this version

| ID | Description | Comments |
|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 22398 | Present and Proposed section: <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 | Input fields for the ASMF number and DUNS number have been added to the web UI of eAF. When added in the form, the ASMF numbers will be presented as a part of the present and proposed table, not as a separate field below all present and proposed fields like in the interactive pdf. The DUNS number field will only be displayed in the pdf if value is added to that field in the web eAF. The DUNS number is displayed as a part of the organisational information and not as a separate field below all present and proposed fields like in the interactive pdf. |
| 38757 | Application Forms view – Label change to the drop down options | In the application forms list view, the menu options on the right hand side dropdown selection now indicate 'Coming soon' for those features that are not yet available (for example Copy Application). |
| 40214 | Image resize issue | The images are now displayed in a legible format in the present and proposed fields. The fields in present and proposed can be now used as per normal. |
| 27729 | Clicking 'validate' immediately after clicking 'save' throws an error (RPI cannot be blank for CAP products). | The error message is no longer displayed when the RPI is present and even if the 'validate' button is clicked before the packages are loaded. |
| 25396 | Human Variations eAF | Packaged medicinal products are not shown when combining scopes and medicinal products |
| 42871 | 3 new tick boxes related to | The mandatory tick boxes are now available in |

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| | personal data are missing from the Declaration section when SPC, PI or labelling is ticked in Annexed documents section. | 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 | Procedural information: Some mandatory fields are not |

| | | |
|-------|-------------------------|-----------------------------------------------------------------------------------------------------------------------|
| | eAF | 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 | Error after wrong date format for Implementation date |

| | | |
|-------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| | eAF | |
| 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 | Some inactive organisations from OMS available in Contact |

| | | |
|-------|----------------------|----------------------------------------------------------------------------------------|
| | eAF | Person organisation section |
| 25396 | Human Variations eAF | Packaged medicinal products are not shown when combining scopes and medicinal products |
| 24731 | Human Variations eAF | The Proposed Package Item Content is not linked to Application Form |

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

Version Goal: PLM Portal bug fix release

Date: 23/01/2023

Environment: production

Version content (testable functionalities/use cases)

Version content

| Functionality/use case | Component | Short description |
|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Implementation of the web based human variation application form | Human Variations eAF Version 1.0.1.4 | This release note is for the BUGFIX version 1.0.1.4 release go-live 23/01/2023 |
| Update of the human readable pdf export | PDF Version 2.0.2.2* *Please note that the newly introduced 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 23/01/2023 |

Issues fixed in this version

| ID | Description | Comments |
|-----------------|------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 24184 – web eAF | Add a link to the Guidance for applicants on precise scope | The Guidance for applicants for the preparation of the 'precise scope' section of the variation application form is now available via a link in the Precise Scope |

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| | | 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 |
| 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 | Finalisation section - Proof of payment - able to select either Yes or |

| | | |
|-------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| | Variations eAF | NO |
| 23968 | Human Variations eAF | Hyphenations are incorrect in tab type of changes, in the view scope and description and in the view conditions and documentation section |
| 23969 | Human Variations eAF | Cannot select more than one organisation in Proposed Organisation field |
| 23971 | Human Variations eAF | Proposal for Organisation Details – Split Text |
| 23974 | Human Variations eAF | Suggestion - Scope section - Information is not displayed in a user-friendly manner. |
| 24006 | PLM Portal | Refresh button producing error on Application list view |
| 24905 | PDF | Country name shown is long version in PDF |
| 24907 | Human Variations eAF | Select all checkbox does not "Select All" in "Proposed Changes" section |
| 25269 | Human Variations eAF | Product select screen shows 0/0 product presentation |
| 25301 | Human Variations eAF | Precise scope and background for information section not saved |
| 25395 | Human Variations eAF | Some inactive organisations from OMS available in Contact Person organisation section |
| 25396 | Human Variations eAF | Packaged medicinal products are not shown when combining scopes and medicinal products |
| 24731 | Human Variations eAF | The Proposed Package Item Content is not linked to Application Form |

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

Version Goal: Go-Live PLM Portal

Date: 28/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

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

Issues fixed in this version

| ID | Description | Comments |
|------------------|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 27878 – FHIR XML | Dissonance between the packaged products selected on the DADI form and the 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 | Form cannot be used for variations that add new presentation |

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

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| 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 |

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| 23971 | Human Variations eAF | Proposal for Organisation Details – Split Text |
| 23974 | Human Variations eAF | Suggestion - Scope section - Information is not displayed in a user-friendly manner. |
| 24006 | PLM Portal | Refresh button producing error on Application list view |
| 24810 | PLM Portal | Email template populate incorrectly after sending "Notify" email to co-author |
| 24905 | PDF | Country name shown is long version in PDF |
| 24907 | Human Variations eAF | Select all checkbox does not "Select All" in "Proposed Changes" section |
| 25269 | Human Variations eAF | Product select screen shows 0/0 product presentation |
| 25301 | Human Variations eAF | Precise scope and background for information section not saved |
| 25395 | Human Variations eAF | Some inactive organisations from OMS available in Contact Person organisation section |
| 25396 | Human Variations eAF | Packaged medicinal products are not shown when combining scopes and medicinal products |
| 25400 | Human Variations eAF | Incorrect calculation of number of selected scopes in the summary page |
| 24731 | Human Variations eAF | The Proposed Package Item Content is not linked to Application Form |

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

Version Goal: Go-Live PLM Portal

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

Environment: production

Version content (testable functionalities/use cases)

Version content

| Functionality/use case | Component | Short description |
|---------------------------|----------------------|-------------------------------------|
| Implementation of the web | Human Variations eAF | This release note is for the BUGFIX |

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|-------------------------------------------------|---------------------|--------------------------------------------------------------------------------|
| based human variation application form | Version 1.0.1.1 | 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 | Incorrect date sorting for | The list of pdf exports was displayed in random order. |

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|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| eAF | Export window | |
| 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 – for any change that concerns an organisation e.g. change of a manufacturing site, the site must be selected from OMS. For further details on the use of this section please see: European Medicines Agency practical guidance on the application form for centralised type IA and IB variations page 13 |
| 24738 – pdf | <ul style="list-style-type: none"> Removed APPENDIX section Structured changes are shown in section 3 Text in HTML fields is same size as all the PDF | The appendix part of pdf was deleted as non-relevant. The changes are now reflected in the present and proposed section where relevant e.g. ATC code. The text size in Precise scope and Background sections and the Present and Proposed fields is now same size as in all other fields in the pdf making the form content easier to read. |

Known Issues

| ID | Component | Short description |
|------------------|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 27565 | Human Variations eAF | 3 new tick boxes related to personal data are missing from the Declaration section when SPC, PI or labelling is ticked in Annexed documents section. This causes a validation error at time of finalisation of the form. Note: This does not result in business validation error as this is a known bug in the form. |
| Known limitation | PLM Portal | Copy application feature not available yet |
| Known limitation | Human Variations eAF | Cannot select 'includes line extension' when single scope added |
| Known limitation | Human Variations eAF | It is not possible to change the 'Friendly name' |
| Known limitation | Human Variations eAF | Form cannot be used for variations that add new presentation |
| Known limitation | Human Variations eAF | Delay in display of packaged medicinal products in product selection. |
| Known limitation | Human Variations eAF | Delay in automated calculations in Procedural information section e.g. correct calculation of 'grouping' or display of Additional Information section |
| Known limitation | Human Variations eAF | Cannot clone variation scopes added in the form (convenience feature when adding multiple times the same scope) |
| Known limitation | FHIR xml | Commercially Confidential Data not related to the application content/variation present in the FHIR XML |
| Known limitation | Human Variations eAF | The system creates an empty row in summary of Present and Proposed when 'save' is pressed after filling in certain sections. The empty row should be edited to contain the changes or deleted |
| Known limitation | Human Variations eAF | Other Applications – Select EMA Procedure has no related procedures available for selection. Workaround: use the +Add to manually add other ongoing applications |
| Known limitation | Human Variations eAF | Present and Proposed section: ASMF number and DUNS number fields missing from the Web UI. If these need to be provided, please use Precise Scope section or the interactive pdf eAF. |
| 25395 | Human Variations eAF | Some inactive organisations from OMS available in Contact Person organisation section |

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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 |
| 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 |

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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 |
| 23971 | Human Variations eAF | Proposal for Organisation Details – Split Text |
| 23974 | Human Variations eAF | Suggestion - Scope section - Information is not displayed in a user-friendly manner. |
| 24006 | PLM Portal | Refresh button producing error on Application list view |
| 24810 | PLM Portal | Email template populate incorrectly after sending "Notify" email to co-author |
| 24905 | PDF | Country name shown is long version in PDF |
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| 25269 | Human Variations eAF | Product select screen shows 0/0 product presentation |
| 25301 | Human Variations eAF | Precise scope and background for information section not saved |
| 25395 | Human Variations eAF | Some inactive organisations from OMS available in Contact Person organisation section |
| 25396 | Human Variations eAF | Packaged medicinal products are not shown when combining scopes and medicinal products |
| 25400 | Human Variations eAF | Incorrect calculation of number of selected scopes in the summary page |

Version: 1.0.0.0 (Release date 04/11/2022)

Version Goal: Go-Live PLM Portal

Date: 04/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

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

Known Issues

| ID | Component | Short description |
|------------------|----------------------|-----------------------------------------------------------------|
| Known limitation | PLM Portal | Copy application feature not available yet |
| Known limitation | Human Variations eAF | Cannot select 'includes line extension' when single scope added |
| Known limitation | Human Variations eAF | It is not possible to change the 'Friendly name' |
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| 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 |
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