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eSubmissions Web UI Release Notes

This document lists and briefly describes the new features and fixed issues included in the release of the eSubmissions web UI component.

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 eSubmissions Web UI.

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 |
|------------------------------------|--|
| eSubmissions Web UI | The user interface (UI) used by MAHs to generate the delivery file with the metadata needed to submit and process the electronic submissions for the Human and Veterinary medicines application documentation. |
| eSubmission Process | The business process whereby MAHs submit electronically the application documentation to the eSub GW. |
| Notifications/ Acknowledgements | The functionality that sends acknowledgements to MAAs/ MAHs upon certain pre-defined events happening. |
| eSub GW | eSubmission Gateway |

For the purpose of this document, a change request (CR) is defined as an additional functionality that was not included in the original requirements of the software.

For additional information on the PSUR Repository see:

- The [eSubmission Gateway and eSubmission Web Client webpage](#) gives access to all documentation.
- Regular training sessions are being organised. See the [eSubmission Gateway and eSubmission Web Client webpage](#) for more information.
- User guidance documentation on the [eSubmission Gateway and eSubmission Web Client webpage](#) provides answers to most common problems.
- If you encounter any issue that is not addressed by the above, visit the EMA Service Desk portal: <https://servicedesk.ema.europa.eu>

Version: 3.2.2.0

Version Goal: Production release

Date: 27/06/2017

Environment: production

- Version content (testable functionalities/use cases)

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------|--|
| SD-96712 | eSubmissions Web UI | Additional work on UAT comments from previous release <ol style="list-style-type: none">1. Corrections in sync between submission type and submission description.2. Correction in naming of submission description |

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------|---|
| | | <ol style="list-style-type: none"> 3. Applicant/MAH contact information available in notification for pre-submission products 4. ATC code and substance name available in notification as well as UI for pre-submission product. 5. Applicant/MAH customer number available in notification for pre-submission product. 6. Addition of new field to enter rmp version number in case rmp submission type is selected. 7. Addition of new fields when submission type clin-data-pub-fv and clin-data-pub-rp are selected. 8. Allow user to indicate grouping for variations/initial 9. Remove procedure number field for workshare/IG 10. Add a field for maa/initial where user can indicate if product selected is ancillary medicinal product in medical device |
| PSUR-745 | eSubmissions Web UI | Defect fix - After generating xml for reformat/baseline submission type, many submission unit gets enabled which should not be allowed. Also valid submission unit becomes disabled. |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|---|----------|
| SD-107624 | <p>Submission description 'responses to RSI' is shown on the XML delivery file (output) when submission units initial, validation-response, additional-information, consolidating, corrigendum and closing is selected. This does not prevent successful submission and will be addressed in the next release.</p> <p><code><submission_unit>initial</submission_unit></code> <code><submission_desc>Responses to RSI</submission_desc></code></p> | medium |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Version: 3.2.0-RC4

Version Goal: Production release

Date: 05/04/2017

Environment: production

- Version content (testable functionalities/use cases)

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------------------------|---|
| SD-84522 | eSubmissions Web UI | Defect in the back-end of XML delivery file for Veterinary referrals preventing successful submissions using the XML delivery file has been fixed |
| SD-93408 | eSubmissions Web UI | Data protection issue - product contact person name and contact details are no longer displayed in the eSubmission Gateway UI or the XML delivery file |
| SD-93918 | eSubmissions Web UI | Vet domain: for submission type "maa" (all submission unit types) the product name should not be displayed |
| SD-94637 | eSubmissions Web UI | Unable to create delivery file for a signal detection submission with large number of products |
| ESUBWEB-377 | eSubmissions Web UI | When submission type is signal detection and submission format is eCTD and user selects more than one product, user is unable to generate delivery file |
| ESUBWEB-376 | eSubmissions Web UI | Incorrect error message about Epitt number |
| SD-94319 | eSubmissions Web UI | XML delivery files won't create because of β in product name |
| SD-91953 | eSubmission Web – Gateway Filehandler | Referral submission with National product type in other format fails if non-authorized product is not selected |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|----------|----------|
| | | |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Version: 3.2.0-RC2

Version Goal: Production release

Date: 31/03/2017

Environment: production

- Version content (testable functionalities/use cases)

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------|---|
| SD-84522 | eSubmissions Web UI | Defect in the back-end of XML delivery file for Veterinary referrals preventing successful submissions using the XML delivery file has been fixed |
| SD-82460 | eSubmissions Web UI | The correct business rule has been implemented for human Referrals. When nationally authorised product (NAP) presentation is selected the Non-authorized Product name and applicant name fields are not mandatory |
| SD-82464 | eSubmissions Web UI | New fields have been added to the XML delivery file for centralised procedure submissions to integrate Formatted Table Template into the XML delivery file; <ul style="list-style-type: none">• Submission Description field has been added to add granularity to submission unit 'response'• Procedure number should be selected from a list of relevant numbers for 'subsequent submissions after the 'initial' submission for where relevant e.g. variations, renewals etc.• When variation that contains more than one scope is selected, 'grouping of more than one scope' is indicated in the XML• Contact person name and contact details and the MAH name are now auto-filled for visual confirmation on the XML |

| Functionality (*use case) | Component | Comments |
|---------------------------|--------------------------------|--|
| | | delivery file (initial MAA applications are currently excluded) <ul style="list-style-type: none"> When MAA, WS or IG variation are selected with submission unit 'initial' MAH should provide SAP customer number and optional customer reference. These are automatically filled for variations |
| SD-59634 | eSubmissions Web UI | The text in the tooltip for 'Mode' field has been updated to better explain use of this field and discrepancy between EU Module 1 specification |
| SD-41394 | eSubmission Gateway/Web Client | Error code 55 has been split to multiple different error codes for better identification of issues |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|---|----------|
| | When submission type MAA or Extension is selected with submission unit 'responses' it should not be possible to select 'Responses to RSI' | |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Version: 3.1.0-RC1

Version Goal: Production release

Date: 20/02/2017

Environment: production

- Version content (testable functionalities/use cases)

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------|---|
| SD-69226 | eSubmissions Web UI | Additional information is now required for Referral submissions |
| SD-63476 | eSubmissions Web UI | Response time is high for: Search var-type2 National |

| Functionality (*use case) | Component | Comments |
|---------------------------|------------------------|---|
| SD-71769 | eSubmissions Web UI | National product with space at the end of product short names (in Article 57 database) can now be sent successfully via gateway |
| SD-68641 | eSubmissions Web UI | When two packages with same/similar name are send immediately after each other, both submissions trigger acknowledgement |
| SD-64397 | eSubmissions Web UI | For clinical data publication and withdrawal submission types now show withdrawn and surrendered products |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|--|----------|
| SD-72716 | It is not possible to create XML delivery file for initial submission for Ancillary medicinal products. Workaround solution: please submit initial submissions for applications for Ancillary Medicinal Products using filenamng convention. | |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Version: 3.0.0-RC1

Version Goal: Production release

Date: 04/12/2016

Environment: production

- Version content (testable functionalities/use cases)

| Functionality (*use case) | Component | Comments |
|---------------------------|------------------------|---|
| SD-51005 | eSubmissions Web UI | ESubWeb application does not reconnect when File maker database connection is lost because of firewall or other issues |
| SD-57376 | eSubmissions Web UI | Submission of VET MRL and Psur using delivery file |
| SD-63494 | eSubmissions Web UI | Submission of Ancillary medicinal substances in medical devices using delivery file |
| SD-63488 | eSubmissions Web UI | Submission on PASS 107o using delivery files. Submission of PASS 107n, PASS 107o and PASS 107q for Nationally Authorised Products using |

| Functionality (*use case) | Component | Comments |
|---------------------------|-----------|----------------|
| | | delivery file. |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|----------|----------|
| | | |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Version: 2.0.0-RC8

Version Goal: Production release

Date: 06/10/2016

Environment: production

- Version content (testable functionalities/use cases)
-

| Functionality (*use case) | Component | Comments |
|---------------------------|------------------------|--|
| SD-49176 | eSubmissions Web UI | ASMF product selection fix |
| SD-41931/SD-38726 | eSubmissions Web UI | Restricting epitt number for signal detection to 5 digits rather than 6 digits – both these are closed SD's because of workaround and associated problem to be created |
| SD-51712 | eSubmissions Web UI | Issue with referral search |

Bugs fixed for this version (to be tested towards closure)

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| - | - |

Change requests implemented for this version (to be tested towards closure)

| CR id (on clear quest) | Comments |
|------------------------|----------|
| None | - |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|----------|----------|
| | | |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Version: 2.0.0-RC

Version Goal: Production release

Date: 20/09/2016

Environment: production

➤ Version content (testable functionalities/use cases)

➤

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------|--|
| SD-44659 | eSubmissions Web UI | eSubmission Gateway - initial MAA submission has additional zero |
| SD-44638 | eSubmissions Web UI | Removing one of zeros from 7digit pre submission product number we receive from Siamed |

Bugs fixed for this version (to be tested towards closure)

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| - | - |

Change requests implemented for this version (to be tested towards closure)

| | |
|------------------------|----------|
| CR id (on clear quest) | Comments |
| None | - |

Known issues

| | | |
|-------------------------|----------|----------|
| Bug id (on clear quest) | Comments | Severity |
| | | |

Enhancements

| | |
|-------------------------|----------|
| Bug id (on clear quest) | Comments |
| | |

Version: 2.0.0-RCXX

Version Goal: Production release

Date: 25/07/2016

Environment: xcomp, production

- Version content (testable functionalities/use cases)
-

| Functionality (*use case) | Component | Comments |
|----------------------------------|---------------------|--|
| SD-7706 | eSubmissions Web UI | Compliance to the new Specification of "EU Module1 eCTD v.3.0 Please see document below for details of changes: SD 7706-ESub-web changes EMA/345554/2016 https://docs.eudra.org/webtop/drl/objectId/090142b2833d5a6b |
| | eSubmissions Web UI | Implemented points 1,5,6 from document below: Desired_changes_SD 7706 EMA/346669/2016 https://docs.eudra.org/webtop/drl/objectId/090142b28346f89b |
| ESUBWEB-106 | eSubmissions Web UI | <supp_info_for_init_maa> is set to true for referrals when product type is national and Non-authorised product(s)/Herbal product(s) checkbox is ticked |
| ESUBWEB-108 | eSubmissions Web UI | Submission unit is not set to none as described in SD 7706-ESub-web changes |

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------|--|
| ESUBWEB-109 | eSubmissions Web UI | Sequence Number text not same for all submission types |
| ESUBWEB-110 | eSubmissions Web UI | pmf holder name is displayed as blank in UI |
| ESUBWEB-112 | eSubmissions Web UI | No acknowledgement received after submission Human Annual-reassessment via GW |
| ESUBWEB-113 | eSubmissions Web UI | products addition when eCTD is selected as Submission |
| ESUBWEB-114 | eSubmissions Web UI | Human Referrals - National eCTD products - more than 1 product is selected and no errors |
| ESUBWEB-115 | eSubmissions Web UI | Signal -detection - eCTD -- More than 1 product can be selected |
| ESUBWEB-116 | eSubmissions Web UI | Incorrect Error while creating delivery file for |
| ESUBWEB-117 | eSubmissions Web UI | unable to upload reformat/baseline via GW (error - Wrong regulatory activity format: reformat/baseline) |
| ESUBWEB-118 | eSubmissions Web UI | Wrong label for EPIT number in Signal-detection Acknowledgement |
| ESUBWEB-119 | eSubmissions Web UI | No Ack received for Human Var-types |
| ESUBWEB-120 | eSubmissions Web UI | pmf holder: is printed as blank in GW acknowledgement |
| ESUBWEB-121 | eSubmissions Web UI | GW Ack for Pediatric investigation plan has dd-mm at the end of the subject which is not required nor valid for this submission type |
| ESUBWEB-122 | eSubmissions Web UI | Article number not stated in Ack received from GW make it difficult to identify the submission |
| ESUBWEB-123 | eSubmissions Web UI | Remove Sequence number from all Vet Notifications subject line |
| ESUBWEB-124 | eSubmissions Web UI | Nees/VNees & Other enabled for Maa submission type.. |
| ESUBWEB-312 | eSubmissions Web UI | IG & Worksharing number have a # printed in the notification sent via GW |
| ESUBWEB-314 | eSubmissions Web UI | On clicking reset button the values are not refreshed |
| ESUBWEB-316 | eSubmissions Web UI | PIP UI should be reverted back to as is |
| ESUBWEB-318 | eSubmissions Web UI | Product 4461 is not available for selection |
| ESUBWEB-322 | eSubmissions Web UI | Mode shows "IG" and "WS" incorrectly |
| ESUBWEB-324 | eSubmissions Web UI | Wrong instruction text in the Select product field |

| Functionality (*use case) | Component | Comments |
|---------------------------|---------------------|---|
| ESUBWEB-328 | eSubmissions Web UI | Remove paed-46 and pam-p45 from the list |
| ESUBWEB-332 | eSubmissions Web UI | Help text in the "Referral" field displays the following: "Enter EMA Referral No." |
| ESUBWEB-334 | eSubmissions Web UI | Product from pre-submission module of SIAMED not appearing in the Select a product field |
| ESUBWEB-336 | eSubmissions Web UI | RUP is not a valid submission type for EMA submissions (Repeat Use Procedure in decentralized or mutual recognition procedures to include one or more additional member states) |
| ESUBWEB-337 | eSubmissions Web UI | Article 35 is not a referral procedure Article and should be removed from the list of Articles |

Bugs fixed for this version (to be tested towards closure)

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| - | - |

Change requests implemented for this version (to be tested towards closure)

| CR id (on clear quest) | Comments |
|------------------------|----------|
| None | - |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|----------|----------|
| | | |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Version: 1.0.0-RC11

Version Goal: Production release

Date: 23/05/2016

Environment: xcomp, production

Version content (testable functionalities/use cases)

| Functionality (*use case) | Component | Comments |
|--|------------------------|----------|
| Electronic submission of the initial MAA (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the variation type IA, IB, II (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Referral (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the ASMF (Active Substance Master File) (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the PMF (Plasma Master file) | eSubmissions Web UI | |
| Electronic submission of the Art.58 (WHO) | eSubmissions Web UI | |
| Electronic submission of the PSUR/ PSUSA | eSubmissions Web UI | |
| Electronic submission of the Paediatrics | eSubmissions Web UI | |
| Electronic submission of the the Annual-reassessment (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the corrigendum (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Extension (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Lifting – suspension | eSubmissions Web UI | |
| Electronic submission of the Notification-61-3 (HUMAN | eSubmissions Web UI | |

| Functionality (*use case) | Component | Comments |
|---|---------------------|-----------------|
| Medicines) | | |
| Electronic submission of the Paediatrics-article-46 | eSubmissions Web UI | |
| Electronic submission of the Post Authorisation Measure (PAMs) (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Reformat (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Renewal (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Risk management plan (RMP) (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Specific obligation (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Supplemental info (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Transfer of a MA (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the Urgent Safety Restriction (USR) | eSubmissions Web UI | |
| Electronic submission of the Withdrawal of a MA (HUMAN Medicines) | eSubmissions Web UI | |
| Electronic submission of the initial MAA (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the variation type IA, IB, II (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Referral (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the ASMF (Active Substance Master File) (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the the Annual-reassessment (Veterinary Medicines) | eSubmissions Web UI | |

| Functionality (*use case) | Component | Comments |
|---|---------------------|----------|
| Electronic submission of the corrigendum (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Extension (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Lifting – suspension (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Post Authorisation Measure (PAMs) (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Reformat (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Renewal (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Risk management plan (RMP) (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Specific obligation (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Supplemental info (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Transfer of a MA (Veterinary Medicines) | eSubmissions Web UI | |
| Electronic submission of the Withdrawal of a MA (Veterinary Medicines) | eSubmissions Web UI | |

*** Detailed description of the Use Cases for eSubmissions Web UI:**
- UCs-v03.05 [emea_doc_ref_id]
<https://docs.eudra.org/webtop/drl/objectId/0b0142b2832b53b5>

Bugs fixed for this version (to be tested towards closure)

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| - | - |

Change requests implemented for this version (to be tested towards closure)

| CR id (on clear quest) | Comments |
|------------------------|----------|
| None | - |

Known issues

| Bug id (on clear quest) | Comments | Severity |
|-------------------------|----------|----------|
| | | |

Enhancements

| Bug id (on clear quest) | Comments |
|-------------------------|----------|
| | |

Additional information

None.

Installation steps deviating from the deployment guide

None.

Please follow the Deployment Guide available at:

esubWeb-deployment-guide
EMA/16174/2016

<https://docs.eudra.org/webtop/drl/objectId/090142b28332aa20>