23 June 2017
EMA/507917/2016

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 webpageprovides 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 1. Corrections in sync between submission type and submission description. 2. Correction in naming of submission description

Functionality (*use case)	Component	Comments
		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

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 ß in product name
SD-91953	eSubmission Web – Gateway Filehandler	Referral submission with National product type in other format fails if non-authorised 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; • 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 delivery file (initial MAA applications are currently excluded) • 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
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 filenaming 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 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)

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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 referals when product type is national and Non-authorised product(s)/Herbal product(s) checkbox is ticked
ESUBWEB-108	eSubmissions Web UI	Submisson unit is not set to none as described in SD 7706-ESub-web changes
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

Functionality (*use case)	Component	Comments
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
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