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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: 3.7.6.0

Version Goal: Production release

Date: 11/03/2021

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-450435	eSubmissions Web UI XML delivery file EMA internal email notifications	Human and Veterinary domains: <ul style="list-style-type: none">• Where relevant the "Customer reference" field is renamed to "Purchase Order number"• When the user clicks on the 'i' icon next to "Purchase Order number" field an informative message is shown: "Applicants and marketing authorisation holders requiring a purchase order number or similar references on their invoice are encouraged to issue a standing (blanket) purchase order covering all marketing authorisation and/or pharmacovigilance fees levied by the Agency for a given period and to provide such reference to the Agency's accounts receivable service at accountsreceivable@ema.europa.eu. Alternatively, such reference can be provided here."• The error message when "Purchase Order number" is mandatory and the value is missing and the user clicks on Generate Delivery file button, is updated into: "Please provide Purchase Order Number, alternatively type N/A if not applicable".• The customer reference field in the XML file is renamed to PO number.• The customer reference field in the notification email is renamed to PO Number.
SD-459589	eSubmissions Web UI	Human domain only: <ul style="list-style-type: none">• A new mandatory radio button called "Nitrosamine related procedure with "Yes / No" options has been added. This new radio button will be shown for all variation types (Type IA_{IN}, IA, IB, II) when submission unit is initial for centralised products.• This mandatory selection applies for national

Functionality (*use case)	Component	Comments
	XML delivery file EMA internal email notifications	<p>products when variation is type IB or II with mode is WS</p> <ul style="list-style-type: none"> When the user clicks on the 'i' icon next to "Nitrosamine related procedure" field an informative message is shown: "Please confirm (Y/N) that the variation is being submitted in order comply with the recommendations of the article 5(3) scientific opinion on nitrosamines (EMA/H/A-5(3)/1490), i.e. step 3 of the call for review." New field called 'nitrosamine related' has been added in the XML delivery file with possible values yes/no A new "Nitrosamine related procedure" field with possible values Yes / No has been added to the notification email.

Version: 3.7.5.0

Version Goal: Production release

Date: 08/03/2021

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-396033	eSubmissions Web UI	<p>Veterinary domain only:</p> <ul style="list-style-type: none"> For MRL submissions (all types – full, extension, modification, extrapolation), for <i>Initial submissions</i> "Customer number" field is a mandatory field. For MRL submissions (all types – full, extension, modification, extrapolation), submission unit 'additional-info' is enabled and submission unit 'closing' has been

Functionality (*use case)	Component	Comments
	<p>XML delivery file</p> <p>EMA internal email notifications</p>	<p>disabled.</p> <ul style="list-style-type: none"> For Veterinary referral submissions 'response; and 'additional-info' are enabled. The other options 'initial', 'validation-response', 'closing' and 'corrigendum' are disabled. New mandatory customer number field has been included in the XML delivery file for MRL submissions. The format of the auto generated sequence number in the delivery XML of MRL, Vet ASMF, Vet Referral from has been changed from ddMM to yyyy-MM-dd. New fields have been added into the notification email. The fields now available are: Submission type, Submission unit, MRL Substance, Procedure number, Procedure number not assigned, Customer number, Customer reference.

Version: 3.7.3.0 (including changes from v 3.7.1.0)

Version Goal: Production release

Date: 19/11/2020

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-415023	eSubmissions Web UI	<ul style="list-style-type: none"> Human domain only: The business rule for product selection for ASMF submissions has been corrected to always show only the full entry if it exists. If there is only 'pre-submission'

Functionality (*use case)	Component	Comments
		entry H00XXXX with status other than WITHDRAWN the pre-submission entry will be shown.

Functionality (*use case)	Component	Comments
SD-329798	eSubmissions Web UI	<p>Human and Veterinary domains: For submission type "Extension" and submission-unit "Initial", functionality is added to indicate more than one scope in submission (Grouping tick box).</p> <ul style="list-style-type: none"> The grouping tick box has been added in the XML delivery file. The field indicated grouping of scopes has been added to the notification email as filled in the XML
SD-344695	eSubmissions Web UI	<p>Human and Veterinary domains:</p> <ul style="list-style-type: none"> When the "Procedure number" field is available and has not been filled in, when the user clicks the "Generate delivery file" button, an informative pop up message (Yes/No) is shown: "Does procedure number relevant to this submission exist?" <ul style="list-style-type: none"> Clicking "Yes" the user is taken back to form; Clicking "No" the xml file is generated. "Customer Reference" is now a mandatory field for all relevant submission types with submission unit initial (when this field is available in the UI). <p>Human domain only:</p> <ul style="list-style-type: none"> When the "RMP included" field is available and has the value "No", when the user clicks the "Generate delivery file" button, an informative pop up message (Yes/No) is shown: "Is there RMP update submitted with this application?" <ul style="list-style-type: none"> Clicking "Yes" the user is taken back to form; Clicking "No" the xml file is generated. When the field "RMP included" field is has the value "Yes", then field "RMP version number" is mandatory.
SD-352744	eSubmissions Web UI	<p>Human domain only:</p> <ul style="list-style-type: none"> For "PASS107n,o,q" Initial (unit type) submissions when Product Type is "National", 2 new mandatory free text fields

Functionality (*use case)	Component	Comments
	EMA internal email notifications	<p>are now available: Contact person: Contact person email:</p> <ul style="list-style-type: none"> For "PASS107n,o,q" Initial (unit type) submissions when Product Type is "National", when the user clicks the "i" icon next to the Contact person email field, an informative text is displayed: "Please provide the email address of the person who is the responsible contact for this particular procedure. This person will be the recipient of any communication from EMA throughout this procedure." <p>For "PASS107n,o,q" Initial (unit type) submissions when Product Type is "National" the fields contact_name and contact_email have been added to the XML delivery file.</p> <p>The two new fields for "PASS107n,o,q" Initial (unit type) submissions when Product Type is "National" Contact person and Contact person email are shown in the workflow notification email</p> <p>Human and Veterinary domains;</p> <ul style="list-style-type: none"> For all CAP submission types and submission unit types including initial, when the information exists in Siamed the body of the notification is modified in order to add two fields: <ul style="list-style-type: none"> Pharmacovigilance contact information Pediatric contact information (human only)
SD-429152	eSubmissions Web UI	<p>Human domain only: For PASS107n,o,q submission types excluding Submission Unit 'Initial' when Product Type is "National"</p> <p>A check of the correct format of the manually entered PASS procedure number is now performed. The label of the tick box has been changed into "Please tick this box if you cannot find the PASS number from the dropdown list and wish to manually enter the PASS number. Please ensure the number adheres to the correct format - EMEA/H/X/PSX/X/1234 or EMEA/H/X/PSX/X/1234.12"</p> <p>The entering of the PASS107 procedure number is now mandatory.</p>
SD-352739	eSubmissions Web UI	<p>For "PASS107n,o,q" Initial (unit type) submissions when Product Type is "National", the Org EV Code (the Organization ids) from article 57 are now included in XML file.</p>

Functionality (*use case)	Component	Comments
SD-354268	EMA internal email notifications	<p>Changes to the notification emails</p> <ul style="list-style-type: none"> • The subject of the notification email, for all submissions where procedure number is passed is modified to follow the following format: Date Product Name – EMA Product Number – Mode – Procedure Type – Unit type – MAH – Procedure number – Sequence number • The subject of the PSUSA notification is amended in order to follow the following format: Date Product Name – EMA Product Number – Procedure type – MAH – Procedure number – sequence number
SD-373519	eSubmissions Web UI	<p>Procedure Manager and Procedure Assistant retrieved from SIAMED following the procedure or the product number are in the body of the notification email for all CAP submission types and all unit types. Procedure number check takes precedence over product number.</p>
SD-151474	eSubmissions Web UI	<p>eSubWeb Veterinary domain only</p> <ul style="list-style-type: none"> • Submission description' field has been added for 'MRL-extension', 'MRL-extrapolation', 'MRL-full', and 'MRL-modification' submission types. When Submission-unit is 'Response' the applicant should select; <ul style="list-style-type: none"> ○ List of Questions ○ List of Outstanding Issues ○ After Provisional MRL <p>The selected submission values for in the UI screen are reflected in the delivery file submission_desc field</p> <p>Changes to the MRL notification email</p> <ul style="list-style-type: none"> • Subject of the notification follows the following format: Date Product Name – EMA Product Number – Mode – Procedure Type – Unit type – MAH – Procedure number – Sequence number • The selected submission values in the UI screen are reflected in the notification. New fields are added and reflected in the body of the notification <ul style="list-style-type: none"> ○ Submission type: values to be 'MRL-extension', 'MRL-extrapolation', 'MRL-full', and 'MRL-modification' ○ Submission unit: value to be 'Response' ○ Submission-description: values 'List of Questions', 'List of Outstanding Issues', 'After Provisional MRL' ○ MRL Substance: MRL substance ○ Procedure number: Procedure number

Functionality (*use case)	Component	Comments
SD-448905	eSubmissions Web UI	<ul style="list-style-type: none"> • The following applies to Veterinary domain: For MRL (all 4 types) "Customer reference" field is available only for initial Submission Units. • The following applies only to Veterinary Submissions: The field "Customer number" for all relevant submission types (when this field is available in the UI) is mandatory for the user to fill. <p>Human domain only:</p> <ul style="list-style-type: none"> • For "PASS107n,o,q" Initial (unit type) submissions when Product Type is "National" the field PO number is mandated and the field is renamed from "PO number" to "customer reference". The PO number field is only present for submission unit 'initial' submission unit. PO number field that appears in the XML delivery file is also changed to use customer_reference instead of PO number field. PO number appears also in the notification email, is renamed and be called 'customer reference' in the email notification • For "PASS107n,o,q" non-initial (unit types) when Product Type is "National" the field "Select Pass Procedure No" is mandatory.
SD-234364	eSubmissions Web UI	<p><i>Submission Type: "Paediatric submission"</i></p> <ul style="list-style-type: none"> • Mandatory drop-down list 'Choose a Procedure Type'. Following procedure types are available for selection: <ul style="list-style-type: none"> ○ Annual report ○ Class-waiver confirmation request ○ Compliance check ○ Condition/indication confirmation request ○ Discontinuation ○ Modification of an agreed PIP ○ Paediatric investigation plan ○ Waiver • Mandatory "Choose a Submission-Unit" drop-down list has been added to the UI. Following submission-units are available for selection: <ul style="list-style-type: none"> ○ Additional information ○ Answer to PDCO's request for information ○ Answer to PDCO's request for modification

Functionality (*use case)	Component	Comments
		<ul style="list-style-type: none"> ○ Notification of change ○ Pre-submission interaction ○ Re-examination ○ Request for clarification interaction ○ Revocation ○ Submission (application) ○ Validation response ○ Withdrawal <ul style="list-style-type: none"> • "Submission description" field has been added to the UI. This field is only available for selected submission-units. Following submission descriptions are available for selection where applicable: <ul style="list-style-type: none"> ○ Applicant change due to take-over by new legal entity ○ Applicants particulars' change ○ Authorised contact person change ○ Public enquiry contact change ○ Response to Day 30 PDCO discussion ○ Response to Day 90 PDCO discussion • The existing "Pip number" field has been renamed to "Procedure number" field. Procedure number field completion is optional or mandatory depending on the procedure type. When the field is mandatory, the procedure number should be provided in a specific format. The details are included in the information pop up: "Paediatric procedure number is to be found on all procedural documents (EMA decision, PDCO opinion, Summary report) and communications sent to the applicant via EudraLink. It would have one of the following formats: EMEA-xxxxxx EMEA-xxxxxx-PIPxx-yy EMEA-xxxxxx-PIPxx-yy-Mxx EMEA-Cx-xxxxxx-PIPxx-yy-Mxx." • Mandatory free text field called "Active substance (INN)" has been added. It includes the "i" icon with the following pop up text: "Recommended INN, EU Pharmacopoeia

Functionality (*use case)	Component	Comments
		<p>name, common name or exact scientific/chemical name in this order of descending preference."</p> <ul style="list-style-type: none"> Optional "RPI" field has been added to the UI. It includes the "i" icon which will include the pop-up text "Research Product Identifier: https://iris.ema.europa.eu/" Mandatory "Contact person's email address" field has been added for notification of change submission units. An "I" icon is added with the following the pop-up text: 'Please provide the email address of the person who is the responsible for this notification of change. This person will be the contacted of the Notification cannot be processed' <p><i>Changes to the XML Delivery file</i></p> <ul style="list-style-type: none"> The existing pip_number has been renamed to Procedure_number New fields have been added (e.g. procedure_type) <p><i>Changes to the notification email</i></p> <ul style="list-style-type: none"> The subject of the notification email follows the following format: Date – EMA Product Number – Mode – Procedure Type – Unit type – MAH – Procedure number – Sequence number The fields from the UI are also added to the body of the notification email.

Version: 3.7.0.7

Version Goal: Production release

Date: 23/06/2020

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-395039	eSubmissions Web UI	Human domain only: When submission type maa is selected with submission unit initial the label name for the tick box has been changed from <i>Is this ancillary device</i> to Medical Device Related Consultation . The change does not affect the tick box or related business rules. The label name is also changed in the XML delivery file for initial maa and for all submissions that contain products which have been authorised and have EMA number beginning with EMEA/H/D/. The label change is also reflected in the workflow notification email for initial maa submissions where relevant.

Version: 3.7.0.5 Hot Fix

Version Goal: Production release

Date: 05/05/2020

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-391585	eSubmissions Web UI	Human domain only: A new "Covid19 related" radio button with Yes /

Functionality (*use case)	Component	Comments
		<p>No options has been added for submission types:</p> <ul style="list-style-type: none"> • Maa • Extension • var-type2

Version: 3.7.0.3 Hot Fix

Version Goal: Production release

Date: 28/02/2020

Environment: production

➤ Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-367942	eSubmissions Web UI	<p>The product and substance name of a VET non-authorized ASMF product is now not displayed in the UI and the delivery XML.</p> <p>Changes applied also in UI structured order, where selection of the product, when in ASMF-Vet, is in link with the ASMF Procedure.</p> <p>Details breakdown:</p> <ul style="list-style-type: none"> - In case of a valid authorized product, the product will be available in "Select a Product". Product and substance names are displayed. - In case of a pending authorization product or unauthorized product, the product will be available in "Select a Product". Product and substance names are not displayed.

Version: 3.7.0.2 Hot Fix

Version Goal: Production release

Date: 10/02/2020

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-281588	eSubmissions Web UI	Human and Veterinary domains; Added names of PA and PM resource (procedure level) likewise Pediatric and Pharmacovigilance (product level) for all post authorization procedures in Gateway notification email and for all relevant submission types and submission units excluding "Initial" submission unit.
SD-313778	eSubmissions Web UI	Veterinary domains; Change to display entries with product number only when product selected is in pre-submission stage in SIAMED and functionality to manually enter ASMF details for Veterinary submissions.

Version: 3.7.0.1

Version Goal: Production release

Date: 30/10/2019

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-281130	eSubmissions Web UI	Human and Veterinary domains; Added message on the eSubmission Gateway delivery file UI

Functionality (*use case)	Component	Comments
		screen for Human and Veterinary Submissions.
SD-280258	eSubmissions Web UI	Human and Veterinary domains; 'Request for change of Applicant' tick box is replaced with mandatory Yes/No radio buttons. Error message included where selection has not been made.
SD-272109	eSubmissions Web UI	Human domain only; PAM-xxx procedures now include submission unit 'consolidating'. Ability to indicate if a PAM-xxx procedure consolidation submission includes a withdrawal.
SD-274165	eSubmissions Web UI	Defect relating to generating a delivery file for PASS 107n, o and q submissions has been fixed.
SD-330549	eSubmissions Web UI	Defect relating to missing error message for the sequence number in the user interface has been fixed.
SD-330557	eSubmissions Web UI	Defect relating to error message to add MAH name before the product is selected in the user interface has been fixed.

Version: 3.7.0.0

Version Goal: Production release

Date: 09/10/2019

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-198987	eSubmissions Web UI	Human and Veterinary domains; Updated message on the mandatory use of eCTD/VneeS on the landing page of the Web UI for Human and Veterinary Submissions
SD-207332	eSubmissions Web UI	Human and Veterinary domains; 'Brexit related procedure' tick box is replaced with mandatory

Functionality (*use case)	Component	Comments
		'Yes / No' radio buttons
SD-177839	eSubmissions Web UI	Human domain only: It is now possible to select the PASS procedure number for subsequent submissions for PASS 107n, 107o and 107q submissions for Nationally Authorised Products. The PASS number selection is not available for initial PASS submissions or for CAPs. If pass procedure number is not found in the available list, user will be able to enter this value manually.
SD-198921	eSubmissions Web UI	Human domain only; Ability to indicate if a consolidation submission includes a withdrawal. For variation and extension procedures when 'includes withdrawal' is selected it is possible to indicate if the withdrawal concerns the whole procedure or is only 'partial'.
SD-298672	eSubmissions Web UI	Human domain only; Related sequence number should contain identical value to the sequence number where submission-unit is either 'Initial' or 'Reformat'.
SD-43190	eSubmissions Web UI	Human domain only; When Nationally Authorised Products are selected for relevant procedures the EV Code is now visible in the Product selection screen
SD-298683	eSubmissions Web UI	Veterinary domain only; Disable the submission unit 'consolidation' for all submission types.
SD-202303	eSubmissions Web UI	Veterinary domain only; alignment of functionalities between human and veterinary domains to include same metadata <ol style="list-style-type: none"> 1. 'Customer reference' field has been added for relevant procedures. 2. ATC code, INN and MAH details have been added for all procedure types except 'maa'. 3. 'Grouping (more than one scope)' has been added for all variation types. 4. For WS/IG procedures the same text for both Human and Veterinary is now used: 'Select WS/IG number'. 5. For WS/IG procedures, the customer number and customer reference fields have been

Functionality (*use case)	Component	Comments
		<p>added.</p> <p>6. For initial MRL submissions where the procedure number is not available a tick box is used to indicate that the procedure number has not been assigned.</p> <p>7. For MRL responses and additional-info the procedure number list shows the relevant MRL applications relating to the substance.</p>

Version: 3.6.0.0

Version Goal: Production release

Date: 06/09/2018

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-172728	eSubmissions Web UI	<p>To allow ASMF submission for products in pre-authorized phase in SIAMED whereby SIAMED does not contain a record for the ASMF number.</p> <p>Add a checkbox besides the Select ASMF number dropdown, when ASMF number is not found user can select this check box, in which case text in select ASMF text field will change to allow the user to manually enter the ASMF number (also give them pattern for ASMF number).</p> <p>In this case validation about ASMF number should be ignored and submission should go to EURS like other cases.</p> <p>The notification should indicate that the user has manually entered the ASMF number.</p>

Functionality (*use case)	Component	Comments
SD-178523	eSubmissions Web UI	To show the related sequence number and RMP in notifications.

Version: 3.5.0.0

Version Goal: Production release

Date: 06/07/2018

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-130295	eSubmissions Web UI	Pass 107 Annex1 Integration - part of Cover letter template. User will be asked to enter PO number for MAH when user selects national products for Pass107 submission types. Notification will display PO number, legal basis and Org EV Code.
SD-130305	eSubmissions Web UI	If one of three submissions types (PASS) are picked, PAM Code list should only show relevant PASS code
SD-161529	eSubmissions Web UI	When WS / IG (mode) procedure is created (initial unit type). Customer number should not be populated but remain as a pattern 0006-----. Customer should be typing correct number
SD-63491	eSubmissions Web UI	Vet Only For referrals, we have clarified the relations between Article number and product type: only for Article 30(3) the product type can be either "Centralised" or "National", for the rest of Articles it can only be "National".

Functionality (*use case)	Component	Comments
SD-158185	eSubmissions Web UI	Notifications will display one extra field NCA country.
SD-173385	eSubmissions Web UI	Display message for human that <i>'The required submission format is eCTD(mandatory for all centrally authorised, DCP and MRP products). Please note that as of January 2019,the mandatory use of eCTD as the submission format will extend to purely national(NP) products.'</i>

Version: 3.4.0.0

Version Goal: Production release

Date: 08/03/2018

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-130295	eSubmissions Web UI	For clinical data fv and rp add procedure number. Procedure number will be of type type2,extension, maa (initial application)
SD-130305	eSubmissions Web UI	For CAPS when application number is captured in delivery xml then it should be displayed in subject of notification.
SD-131449	eSubmissions Web UI	New field added when submission type is renewal and submission unit is initial. This field will have 2 options: 1 year conditional 5 year This should be displayed in notification body
SD-130319	eSubmissions Web UI	For human CAPS when submission unit is closing then give a plus button besides procedure

Functionality (*use case)	Component	Comments
		<p>number.</p> <p>So that more than one procedure number can be added to a single submission.</p> <p>Clicking plus button will add new procedure number field which will be not filtered (all applications from that product) and will be ordered by date.</p>
SD-139405	eSubmissions Web UI	<p>A new validation set for VNeS submission format</p> <ul style="list-style-type: none"> - VNeS (pharmaceutical product) v.2.5 - VNeS (immunological product) v.2.5
SD-144628	eSubmissions Web UI	<p>Add field to indicate brexit related procedure</p> <p>For : VarII IB IA IAin Transfer Notification 61.3 / only for Initial Submission unit type</p>
SD-113238	eSubmissions Web UI	<p>Sliding tool showing RMP (Y/N) + text for Version number box if Y. This will apply to following submission type</p> <p>MAA II IB Ext PAM Renewal</p> <p>-----</p> <p>Added text box to show related Sequence for all types of submissions and unit types</p> <p>-----</p> <p>Please provide the text box (250 char) Product name and number. This is for submission type (Type II, IB) and it's not mandatory; for initial submission Unit.</p> <p>In case identical changes have been/are being applied for outside of a worksharing procedure</p>

Functionality (*use case)	Component	Comments
		for any other centrally authorised medicinal product, please provide the name(s) of the affected product(s).
SD-134758	eSubmissions Web UI	Add Procedure Number for ASMF(Human Only)
SD-63495	eSubmissions Web UI	Signal detection – Submission format – will only receive ECTD and NEES

Version: 3.3.1.0

Version Goal: Production release

Date: 21/10/2017

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-126488	eSubmissions Web UI	Vet-psur - adding submission description field and updating submission format field with updated values
SD-126638	eSubmissions Web UI	Remove ATC CODE and INN from XML for MAA submission type for veterinary submissions
ESUBWEB-579	eSubmissions Web UI	Product name is appearing "undefined" for submission type asmf in gateway filehandler email notification
SD-126057	eSubmissions Web UI	PAM submission code - change in order of items displayed in the drop down menu

Version: 3.3.0.0

Version Goal: Production release

Date: 29/09/2017

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-86003	eSubmissions Web UI	Restrict input values into Referral field in Gateway XML Delivery file UI – vet pre-include the first part of the number as follows: "EMEA-V-A-"
SD-7717	eSubmissions Web UI	Add field submission description for relevant veterinary submission types (RSI for post-authorisation activities where applicable and LoQ/LoOI for Extension and MAA)
	eSubmissions Web UI	Additional options for the submission format value for veterinary submissions to allow automated technical validation using VNeS technical validation criteria (the user needs to indicate if the product is 'pharmaceutical' or 'immunological').
	eSubmissions Web UI	Extra fields in Vet eSub UI to allow the applicant to select the procedure number for post-authorisation procedures where applicable
	eSubmissions Web UI	For veterinary ASMF submissions the submission type can be VNeS or Other (option NeeS has been removed)
SD-90247	eSubmissions Web UI	extra fields in Vet eSub UI Automatically populate values of MAH, INN, Procedure number in the EMA Gateway notifications and EMA eCTD review tool (no change in the xml delivery file UI)

Known issues

Bug id (on clear quest)	Comments	Severity

Enhancements

Bug id (on clear quest)	Comments

Version: 3.2.3.0

Version Goal: Production release

Date: 01/09/2017

Environment: production

- Version content (testable functionalities/use cases)

Functionality (*use case)	Component	Comments
SD-114320	eSubmissions Web UI	<p>Pam code field will be displayed for all pam submission type (except pam-capa) and all pass submission types.</p> <p>This is mandatory field with following values in drop down</p> <ul style="list-style-type: none">• PASS NII Protocol CAT PRAC CHMP 74 Days PAM (H),• PASS NII Protocol PRAC CHMP 74 Days PAM (H)• PASS NINI Protocol CAT PRAC CHMP 74 Days PAM (H)• PASS NINI Protocol PRAC CHMP 74 Days PAM (H)• PASS II Protocol CAT PRAC CHMP 74 Days PAM (H)

Functionality (*use case)	Component	Comments
		<ul style="list-style-type: none"> • PASS II Protocol PRAC CHMP 74 Days PAM (H) • PASS INI (107) submission PRAC only 60 Days (H) • CAT CHMP 60 Days PAM (H) • CAT PRAC CHMP 74 Days PAM (H) • P46 CAT CHMP 60 Days PAM (H) • P46 CHMP only 60 days PAM (H) • CHMP only 60 Days PAM (H) • PRAC CHMP 74 Days PAM (H) <p>There is an info icon explaining details. Opening info icon says "To select the right options, please consult the PAM Submission Form"</p>
SD-111880	eSubmissions Web UI	<p>(Defect)Wrong submission description in xml</p> <p>Submission description(Human Only)</p> <p>-----</p> <p>Possible values</p> <p>Responses to RSI</p> <p>List of Questions</p> <p>List of Outstanding Issues</p> <p>This field is only to be displayed for Human CAPS when submission type is not rmp, pass and pam and submission unit is response.</p>

Functionality (*use case)	Component	Comments
		<p>1) When submission type is maa and extension submission description will show two selectable items; List of Questions and List of Outstanding Issues. Submission description Response to RSI will be disabled in this case.</p> <p>2) For other CAPS submission type (excluding rmp, pass, pam, maa and extension) only Response to RSI will be displayed and default selected.</p>

Known issues

Bug id (on clear quest)	Comments	Severity

Enhancements

Bug id (on clear quest)	Comments

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	<p>Additional work on UAT comments from previous release</p> <ol style="list-style-type: none"> 1. Corrections in sync between submission

Functionality (*use case)	Component	Comments
		<p>type and submission description.</p> <ol style="list-style-type: none"> 2. Correction in naming of submission description 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	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. <submission_unit>initial</submission_unit> <submission_desc>Responses to RSI</submission_desc>	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

Functionality (*use case)	Component	Comments
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-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

Functionality (*use case)	Component	Comments
		<p>for visual confirmation on the XML delivery file (initial MAA applications are currently excluded)</p> <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
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)
-

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

Functionality (*use case)	Component	Comments
ESUBWEB-106	eSubmissions Web UI	<supp_info_for_init_maa> is set to true for referrals when product type is national and Non-authorized 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
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

Functionality (*use case)	Component	Comments
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	

Functionality (*use case)	Component	Comments
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 Medicines)	eSubmissions Web UI	
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	

Functionality (*use case)	Component	Comments
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	
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	

Functionality (*use case)	Component	Comments
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>