



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmission Gateway Delivery file User Interface v 3.7.3.0 – new functionality

Changes introduced in v3.7.3.0



- SD-415023 Business rule change for product selection for ASMF submissions
- SD-329798 eSubmission Gateway XML delivery file UI - missing functionality for Extension
- SD-344695 Mandatory entry for customer reference where relevant. Reminder to fill in procedure number where applicable.
- SD-352744 Contact person attributes for PASS107n,o,q submissions
- SD-429152 Check of the correct format of PASS107 procedure number
- SD-448905 PASS107 submissions for NAPs – the PO number field renamed
- SD-151474 Addition of Submission Description for MRL submissions types
- SD-234364 The version 3.7.3.0 introduces a major change in the eSubmission Gateway delivery files for **Paediatric Submissions** – details on these changes are described in a **separate presentation** as well as at the end of this presentation



SD-415023 Product selection for ASMF procedures (H only)

Select ASMF:

Please tick this box if you cannot find the ASMF number from the dropdown list and wish to manually enter the ASMF number. Please ensure the number adheres to the correct format - EMEA/ASMF/XXXXX or EU/ASMF/XXXXX

ASMF number:
Substance name:

Select a Product:

Product EMA number:
Product short name:

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 If there is only 'pre-submission' entry H00XXXX with status other than WITHDRAWN the pre-submission entry will be shown.

This will prevent incorrect selection by the user



SD-329798 - Ability to indicate grouping of more than 1 scope for Extension submissions (H & V)

Choose a submission type: [*]	Choose a Submission-Unit: [*]	Mode: [*] ⓘ
extension ▾	initial ▾	Single Product ▾

Grouping (more than one scope):



It is now possible to indicate for both Human and Veterinary domains that the Extension application is part of grouped application where more than 1 scope are grouped.

This option is available for the 'initial' submission of Extension application



SD-344695 Mandatory entry of customer reference (H and V)

- The “**Customer reference**” is now a **mandatory** field for all relevant submission types with submission unit initial

Customer number: * 	Customer reference: * 
<input type="text" value="00006_____"/>	<input type="text" value="Enter customer reference"/>

- Please provide customer number
- Please provide Purchase Order Number i.e. the Customer Reference Number, alternatively NA if not applicable



SD-344695 Reminder on procedure number (H&V)/RMP (H)

A reminder has been included to prompt the user to select a "**Procedure number**" where available:

Warnings

Does procedure number relevant to this submission exist?
Is there RMP update submitted with this application?

Yes No

- 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?"
 - Clicking "Yes" the user is taken back to form;
 - Clicking "No" the xml file is generated.

Human domain only:

- When the "RMP included" field is available and has the value "No", when the user clicks the "Generate delivery file" button, then an informative pop up message (Yes/No) is shown: "Is there RMP update submitted with this application?"
 - Clicking "Yes" the user is taken back to form;
 - Clicking "No" the xml file is generated.
- When the field "RMP included" field is available in the eSubWeb screen and has the value "Yes", then field "RMP version number" is **mandatory**

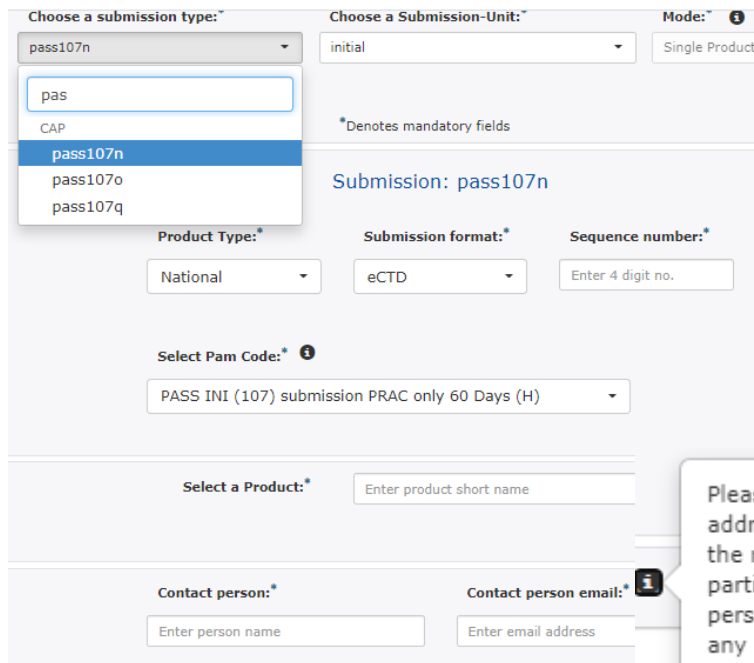
RMP included: Yes

RMP version Number*

Enter RMP version Numbe

- Please enter RMP version number

SD-352744 contact person name and email fields for Human initial PASS107 n, q, o submissions for NAPs only



The screenshot shows a web form for selecting a submission type. A dropdown menu is open for 'Choose a submission type:', showing options: pas, CAP, pass107n (highlighted), pass107o, and pass107q. Other fields include 'Choose a Submission-Unit:' set to 'initial', 'Mode:' set to 'Single Product', 'Product Type:' set to 'National', 'Submission format:' set to 'eCTD', 'Sequence number:' with a prompt 'Enter 4 digit no.', 'Select Pam Code:' set to 'PASS INI (107) submission PRAC only 60 Days (H)', 'Select a Product:' with a prompt 'Enter product short name', 'Contact person:' with a prompt 'Enter person name', and 'Contact person email:' with a prompt 'Enter email address'. A note icon is present next to the 'Contact person email:' label.

New mandatory fields for **Contact person name** and **Contact person email** address have been added for **initial PASS 107n, o and q** submissions for **Nationally Authorised Products** (human domain only)

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.



SD-429152 Check of the correct format of PASS107 n, q, o procedure number for NAP only response submissions

Select Pass Procedure No: *

Enter Pass Number (format EMEA/H/X/PSX/X/1234 or EMEA/H/X/PSX/X/1234.12)

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

It is now mandatory to provide the **PASS procedure number** for **PASS 107n, o and q** submissions for **Nationally Authorised Products** (human domain only). The format of the PASS procedure number when entered manually is checked. The label of the field has been changed to reflect the correct format.

- Please provide the Pass Procedure No
- Please ensure Select Pass Procedure No adheres to the correct format - EMEA/H/X/PSX/X/1234 or EMEA/H/X/PSX/X/1234.12, for example EMEA/H/N/PSR/J/0026 or EMEA/H/C/PSP/S/0074.3



SD-448905 The PO number field has been renamed and made mandatory for PASS107 n, q, o submissions for NAPs

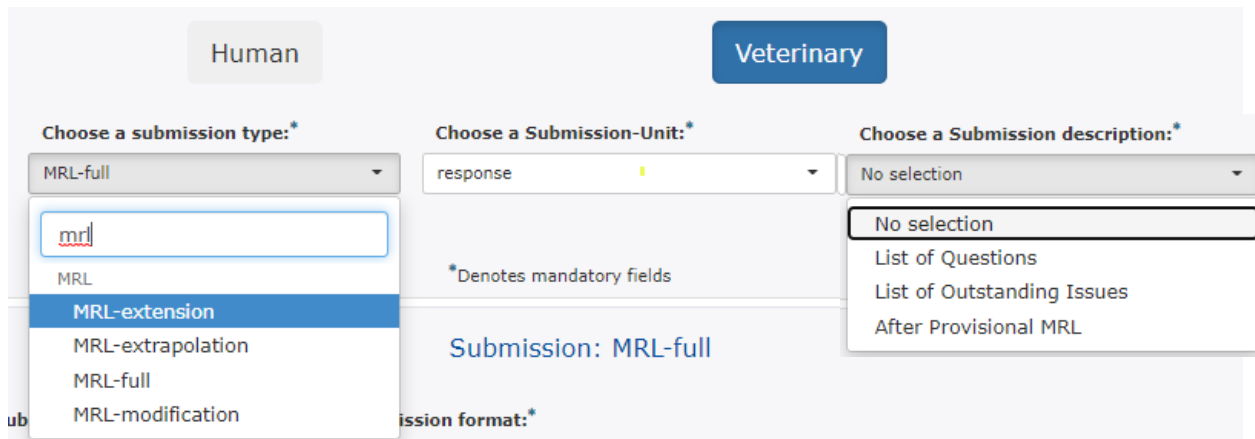
The name of the field has been changed to align with other submission types (from PO number to Customer reference).

It is now mandatory to provide the **Customer Reference** for **intial PASS 107n, o and q** submissions for **Nationally Authorised Products** (human domain only).

MAH name	Customer Reference* ⓘ
OTC CONCEPTS LTD	<input type="text"/>
ANTISEPTICA DR. HANS-JOACHIM MOLITOR GMBH	<input type="text"/>

- Please provide Purchase Order Number i.e. the Customer Reference Number, alternatively NA if not applicable

SD-151474 Addition of Submission Description for MRL submissions



Human **Veterinary**

Choose a submission type:*
 MRL-full
 MRL
MRL-extension
 MRL-extrapolation
 MRL-full
 MRL-modification

Choose a Submission-Unit:*
 response

Choose a Submission description:*
 No selection
 No selection
 List of Questions
 List of Outstanding Issues
 After Provisional MRL

*Denotes mandatory fields

Submission format:*
 Submission: MRL-full

A new mandatory submission description field has been added for all **response** submissions for **MRL submissions**

SD-344695
 The customer reference is now mandatory for all 'initial' MRL submissions.

SD-448905
 The customer reference is not required for any non-initial submissions.

Customer reference:* ⓘ

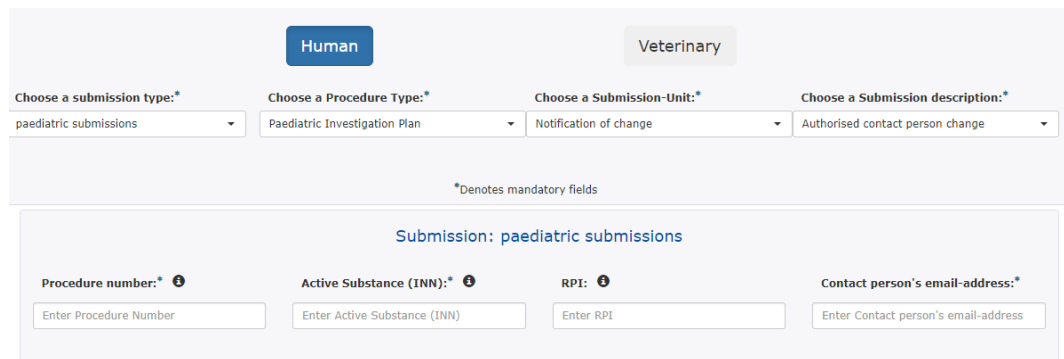
• Please provide Purchase Order Number i.e. the Customer Reference Number, alternatively NA if not applicable



Summary of changes in the Paediatric delivery files – SD-234364

- The version 3.7.3.0 introduces a major change in the eSubmission Gateway delivery files for **Paediatric Submissions** ([Paediatric Regulation](#))
- Various mandatory and optional, fields have been introduced enabling processing of submissions more efficiently and to provide attributes which will enable the paediatric submissions to be searchable in the Common Repository in future

Paediatric submissions – create delivery file



Human Veterinary

Choose a submission type:* paediatric submissions

Choose a Procedure Type:* Paediatric Investigation Plan

Choose a Submission-Unit:* Notification of change

Choose a Submission description:* Authorised contact person change

*Denotes mandatory fields

Submission: paediatric submissions

Procedure number:*


Active Substance (INN):*

RPI:

Contact person's email-address:*

The screen is divided into 2 sections:

Upper section contains drop-down lists to choose from in order to describe the purpose of your submission.

Fields in lower section are free-text to complete accordingly to the guidance text provided in  in order to identify the submission subject.

The required data input depends on the selected Procedure type.

The user will be required to complete all mandatory fields marked with asterisk (*)

Procedure Type

Choose a Procedure Type:*

Paediatric Investigation Plan ▼

- No selection
- Annual report
- Class-waiver confirmation request
- Compliance check
- Condition/indication confirmation request
- Discontinuation
- Modification of an agreed PIP
- Paediatric Investigation Plan
- Waiver

Select the **Procedure Type** from the **dropdown** list to reflect your submission's content.

Depending on the selected Procedure Type various **Submission units** will become available.

Overview with further information is available in "Paediatric submission guidance"



Submission Unit

Choose a Submission-Unit:*

Submission (application) ▼

- No selection
- Additional information
- Answer to PDCO's request for information
- Answer to PDCO's request for modification
- Notification of change
- Pre-submission interaction
- Re-examination
- Request for clarification interaction
- Revocation
- Submission (application)
- Validation response
- Withdrawal

Select the relevant **Submission-Unit** from the **dropdown** list to further define your submission's content.

The **submission unit** is used in conjunction with the **procedure type** i.e. you'll be able to select only options that are applicable to the particular Procedure Type (options that are not applicable for the selected Procedure Type will display in grey font and they cannot be selected).



Submission Description

Choose a Submission description:*

No selection ▼

No selection

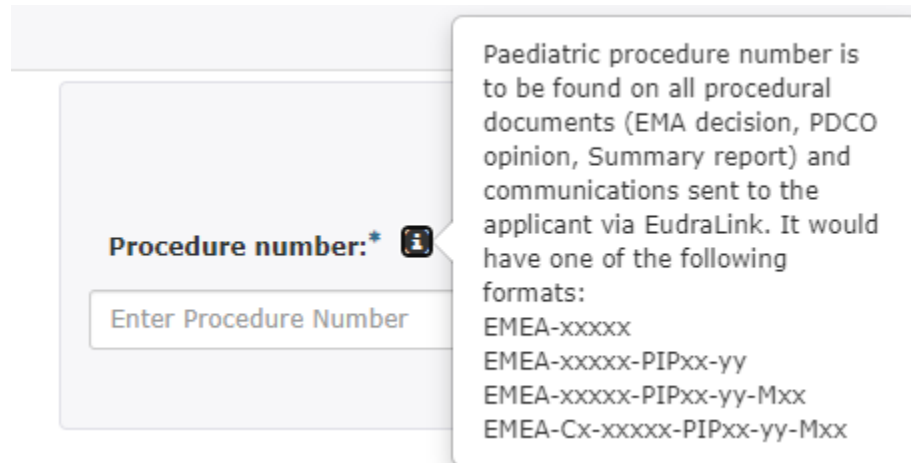
- Applicant change due to take-over by new legal entity
- Applicant particulars' change
- Authorised contact person change
- Public enquiry contact change
- Response to Day 30 PDCO discussion
- Response to Day 90 PDCO discussion

Where applicable*, **select** the most relevant **Submission description** from the **dropdown** list.

* This field is used in conjunction with Submission-Units:

- **'Additional Information'** (to be used when invited to provide responses to PDCO discussion) and
- **'Notification of change'** (to provide further clarity on the requested change scope; if more options are applicable, select the most relevant).

Procedure number



Procedure number:* ⓘ

Enter Procedure Number

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

Depending on the selected **Procedure type** and **Submission unit** the paediatric **Procedure number** is either mandatory or an optional field.

The paediatric procedure number can be found on any procedural document, e.g. Summary report or EMA decision on PDCO opinion and will have a format as described in the information box available (consult Procedural Guidance for further details).



Active Substance (INN)

SUBMISSION

Active Substance (INN):* ⓘ

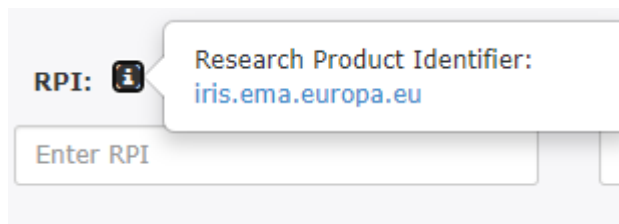
Enter Active Substance (INN)

Recommended INN, EU Pharmacopoeia name, common name or exact scientific/chemical name in this order of descending preference.

The **Active Substance (INN)** is a mandatory field.

Either the recommended INN, EU Pharmacopoeia name, common name or exact scientific/chemical name as per your submission should be provided (consult Procedural Guidance for further details).

Research Product Identifier i.e. RPI




The screenshot shows a user interface for entering a Research Product Identifier (RPI). On the left, the label "RPI:" is followed by an information icon. Below this is a text input field with the placeholder text "Enter RPI". To the right of the input field is a tooltip box containing the text "Research Product Identifier: iris.ema.europa.eu".

The **RPI** is an optional field to complete Research Product Identifier if available at the time of the paediatric submission.

The RPI is generated by [IRIS](#).

Contact person's email address

Contact person's email address:* 

Enter Contact person's email-address

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.

The **Contact person's email address** is a mandatory field applicable only for Submission-Unit **Notification of change**.

Email address of the person who is to be contacted if the Notification cannot be processed (e.g. if the submission is incomplete).



Any questions?

Further information

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