



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## eSubmission Gateway Delivery file User Interface v 3.7.3.0 – new functionality

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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 If there is only 'pre-submission' entry H00XXXX with status other than WITHDRAWN the pre-submission entry will be shown.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: *
<div>extension</div>	<div>initial</div>	<div>Single Product</div>

**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

<b>Customer number:</b> *	<b>Customer reference:</b> *
<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:

A dialog box titled "Warnings" with a light gray background. It contains two lines of text: "Does procedure number relevant to this submission exist?" and "Is there RMP update submitted with this application?". At the bottom right, there are two buttons labeled "Yes" and "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:

A form section with a light gray background. It starts with "RMP included:" followed by a blue toggle switch and the word "Yes". Below this is "RMP version Number" with a red asterisk. Underneath is a text input field with the placeholder "Enter RMP version Number".

- Please enter RMP version number

- 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**

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

Choose a submission type:\*

pass107n

pas

CAP

pass107n

pass107o

pass107q

Choose a Submission-Unit:\*

initial

Mode:\*

Single Product

\*Denotes mandatory fields

Submission: pass107n

Product Type:\*

National

Submission format:\*

eCTD

Sequence number:\*

Enter 4 digit no.

Select Pam Code:\*

PASS INI (107) submission PRAC only 60 Days (H)

Select a Product:\*

Enter product short name

Contact person:\*

Enter person name

Contact person email:\*

Enter email address

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

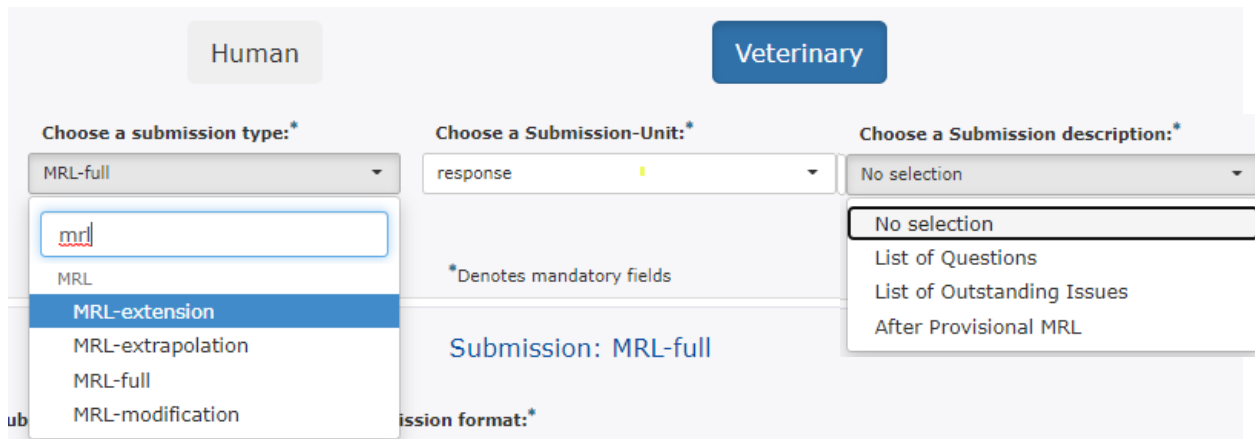
The name of the field has been changed to align with other submission types (from PO number to Customer reference).

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

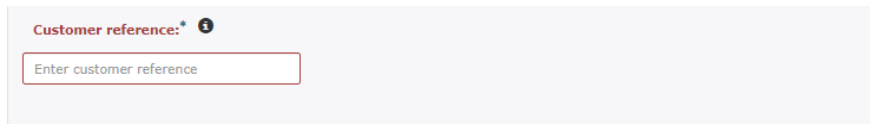


The screenshot shows the 'Veterinary' tab selected. There are three dropdown menus: 'Choose a submission type:' with 'MRL-full' selected, 'Choose a Submission-Unit:' with 'response' selected, and 'Choose a Submission description:' with 'No selection' selected. A fourth dropdown menu is open below 'Choose a submission type:', showing options: 'MRL', 'MRL-extension' (highlighted), 'MRL-extrapolation', 'MRL-full', and 'MRL-modification'. A fifth dropdown menu is open below 'Choose a Submission description:', showing options: 'No selection', 'List of Questions', 'List of Outstanding Issues', and 'After Provisional MRL'. A text input field contains 'mrl'. A note states '\*Denotes mandatory fields'. The submission format is '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.



The screenshot shows the 'Customer reference:' field with a red asterisk and an information icon. Below it is a text input field with the placeholder text 'Enter customer reference'.

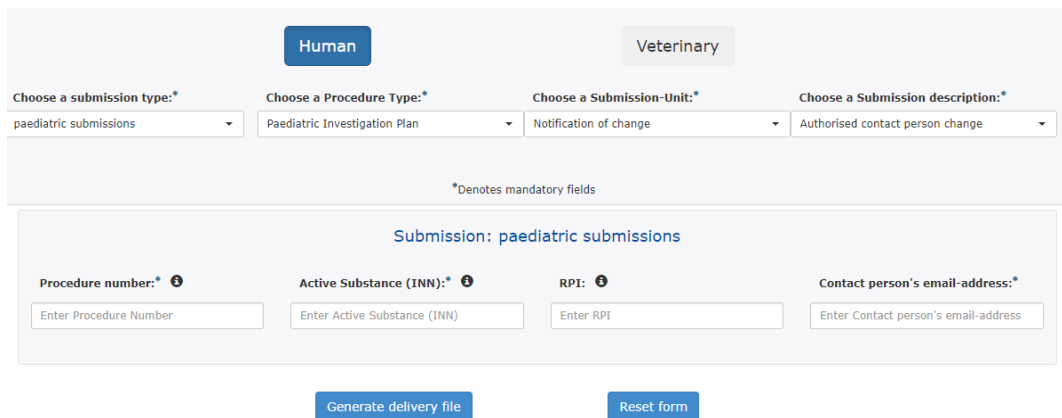
- Please provide Purchase Order Number i.e. the Customer Reference Number, alternatively NA if not applicable



# 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



The screenshot shows a web interface for creating a delivery file for paediatric submissions. At the top, there are two tabs: 'Human' (selected) and 'Veterinary'. Below the tabs, there are four dropdown menus for selection: 'Choose a submission type:\*' (paediatric submissions), 'Choose a Procedure Type:\*' (Paediatric Investigation Plan), 'Choose a Submission-Unit:\*' (Notification of change), and 'Choose a Submission description:\*' (Authorised contact person change). A legend indicates that an asterisk (\*) denotes mandatory fields. Below these selections, the submission is identified as 'paediatric submissions'. There are four input fields: 'Procedure number:\*' (with an information icon), 'Active Substance (INN):\*' (with an information icon), 'RPI:' (with an information icon), and 'Contact person's email-address:\*'. Each field has a placeholder text: 'Enter Procedure Number', 'Enter Active Substance (INN)', 'Enter RPI', and 'Enter Contact person's email-address' respectively. At the bottom, there are two buttons: 'Generate delivery file' and 'Reset form'.

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

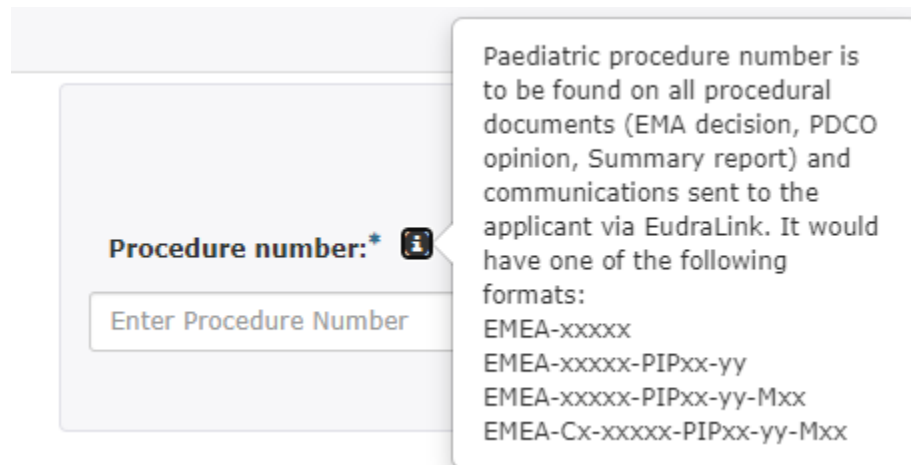
- Applicant change due to take-over by new legal entity
- Applicant particulars' change
- Authorised contact person change
- Public enquiry contact change
- Response to Day 30 PDCO discussion
- Response to Day 90 PDCO discussion

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



The screenshot shows a web form with a label 'Procedure number: \*' and an information icon. Below the label is a text input field with the placeholder 'Enter Procedure Number'. An information tooltip is displayed next to the icon, containing the following text:

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:

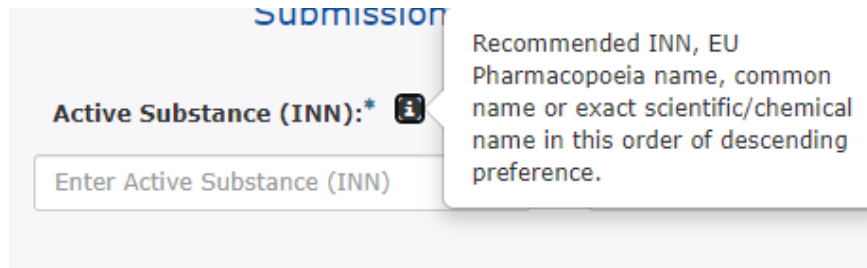
- EMEA-xxxxxx
- EMEA-xxxxxx-PIPxx-yy
- EMEA-xxxxxx-PIPxx-yy-Mxx
- EMEA-Cx-xxxxxx-PIPxx-yy-Mxx

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)

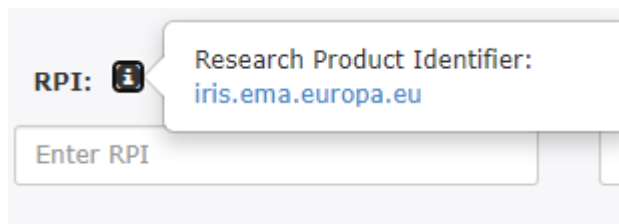


The screenshot shows a form titled "SUBMISSION" with a field labeled "Active Substance (INN):\*" next to an information icon. Below the label is a text input box containing the placeholder "Enter Active Substance (INN)". A tooltip is displayed next to the information icon, containing the text: "Recommended 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

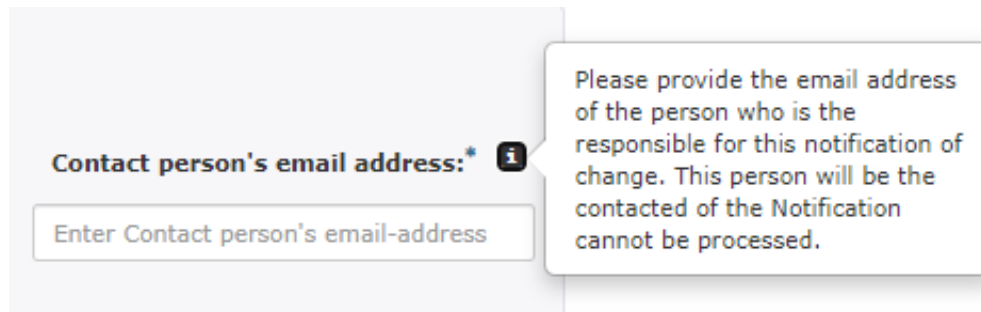


The screenshot shows a user interface for entering a Research Product Identifier (RPI). On the left, the label "RPI:" is followed by an information icon. To the right, a tooltip box contains the text "Research Product Identifier:" and the URL "iris.ema.europa.eu". Below this, there is a text input field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

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](https://iris.ema.europa.eu).

## Contact person's email address



The screenshot shows a form field labeled "Contact person's email address:" with an asterisk and an information icon. Below the label is a text input box with the placeholder text "Enter Contact person's email-address". A tooltip is displayed next to the field, containing the following 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."

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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