



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmission Web UI (Delivery File UI)

What's new for **Paediatric Submissions**

V3.7.1.0

Presented by Kristiina Puusaari on 11th November 2020

An agency of the European Union

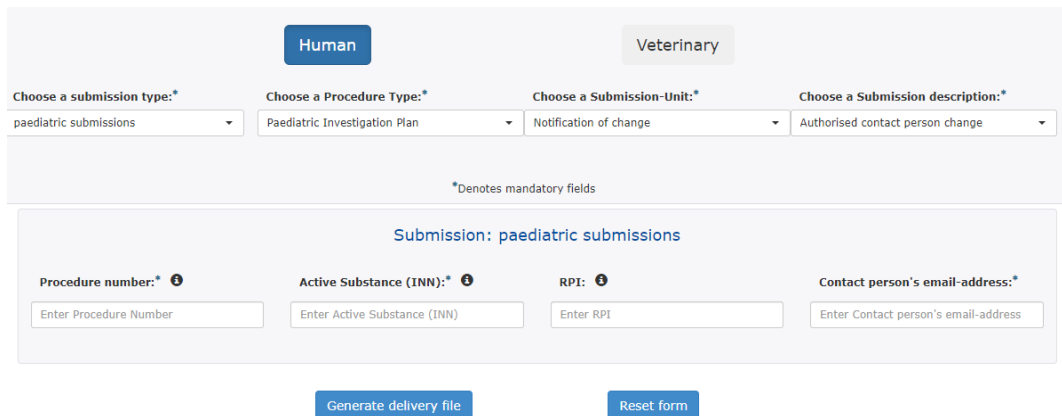




Summary of changes in the Paediatric delivery files

- The version 3.7.1.0 introduces a major change in the eSubmission Gateway delivery files for **Paediatric Submissions** ([Paediatric Regulation](#))
- Various new 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

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:* Enter Procedure Number

Active Substance (INN):* Enter Active Substance (INN)

RPI: Enter RPI

Contact person's email-address:* Enter Contact person's email-address

Generate delivery file 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 **i** 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

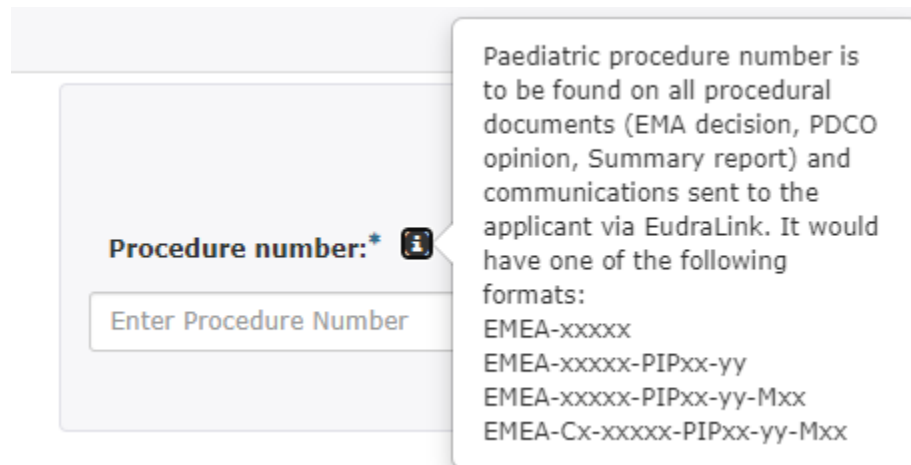
- Applicant change due to take-over by new legal entity
- Applicant particulars' change
- Authorised contact person change
- Public enquiry contact change
- Response to Day 30 PDCO discussion
- Response to Day 90 PDCO discussion

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):* ⓘ

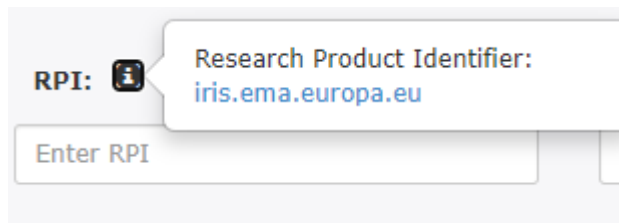
Enter Active Substance (INN)

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 image shows a screenshot of a web form. On the left, there is a label 'RPI:' followed by a small icon of a person. Below this is a text input field with the placeholder text 'Enter RPI'. A tooltip box is positioned above the input field, containing the text 'Research Product Identifier:' followed by the URL '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

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

[EMA Service Desk](#) for technical support

[ASK EMA](#) for any questions regarding paediatric submissions

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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