



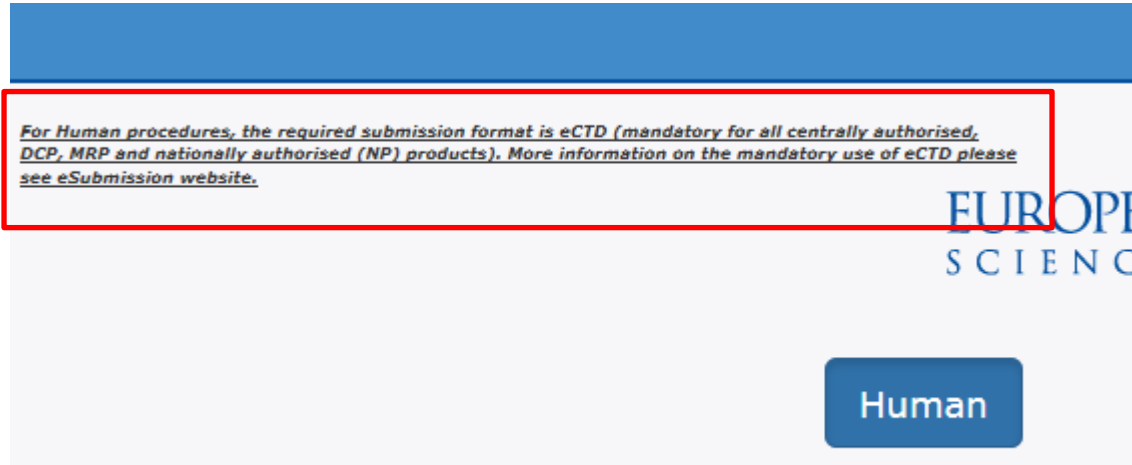
EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## eSubmission Web Client v 3.7.0.0 – new functionality

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Changes introduced in v3.7.0.0





Human and Veterinary domains;  
Updated message on mandatory use of eCTD/VneeS on the landing page of the Web UI for Human and Veterinary Submissions





*For Human procedures, the required submission format is eCTD (mandatory for all centrally authorised, DCP, MRP and nationally authorised (NP) products). More information on the mandatory use of eCTD please see [eSubmission website](#).*



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

Human

Veterinary

Choose a submission type:\*

transfer-ma

Choose a Submission-Unit\*

initial

Mode:\*

Single Product

\*Denotes mandatory fields

Submission: transfer-ma

Product Type:\*

Centralised

Submission format:\*

eCTD

Sequence number:\*

Enter 4 digit no.

Related sequence:

Enter related sequenc

Brexit related procedure:\*

Yes  No

Human and Veterinary domains; 'Brexit related procedure' tick box is replaced with mandatory Yes / No radio buttons

*For Human procedures, the required submission format is eCTD (mandatory for all centrally authorised, DCP, MRP and nationally authorised (NP) products). More information on the mandatory use of eCTD please see eSubmission website.*



Human Veterinary

Choose a submission type:\*  Choose a Submission-Unit\*  Mode:\*

\*Denotes mandatory fields

Submission: pass107n

Product Type:\*  Submission format:\*  Sequence number:\*  Related sequence:

Select Pam Code:\*

Select Pass Procedure No:

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/XXX/PSX/X/1234

Select a Product:\*

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.

*For Human procedures, the required submission format is eCTD (mandatory for all centrally authorised, DCP, MRP and nationally authorised (NP) products). More information on the mandatory use of eCTD please see [eSubmission website](#).*



EUROPEAN MEDICINES AGENCY  
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Human

Veterinary

Choose a submission type:\*

var-type1a

Choose a Submission-Unit\*

consolidating

Mode:\*

Single Product

Includes withdrawal:  Yes

Choose a Withdrawal type\*

No selection  
No selection  
procedure  
partial

\*Denotes mandatory

Submission: v

Product Type:\*

Centralised

Submission format:\*

eCTD

Sequence number:\*

Enter 4 digit no.

Related sequence:

Enter related sequence

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'.

*For Human procedures, the required submission format is eCTD (mandatory for all centrally authorised, DCP, MRP and nationally authorised (NP) products). More information on the mandatory use of eCTD please see [eSubmission website](#).*



EUROPEAN MEDICINES AGENCY  
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Human

Veterinary

Choose a submission type:<sup>\*</sup>

extension

Choose a Submission-Unit<sup>\*</sup>

consolidating

Mode:<sup>\*</sup>

Single Product

Includes  
withdrawal:



Choose a Withdrawal type<sup>\*</sup>

partial

<sup>\*</sup>Denotes mandatory fields

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'.

*For Human procedures, the required submission format is eCTD (mandatory for all centrally authorised, DCP, MRP and nationally authorised (NP) products). More information on the mandatory use of eCTD please see eSubmission website.*



EUROPEAN MEDICINES AGENCY  
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Human

Veterinary

Choose a submission type:\*

notification-61-3

Choose a Submission-Unit\*

initial

Mode:\*

Single Product

\*Denotes mandatory fields

Submission: notification-61-3

Product Type:\*

Centralised

Submission format:\*

eCTD

Sequence number:\*

0000

Related sequence:

0000

Brexit related procedure:\*

Yes  No

Select a Product:\*

ReFacto AF-EMA/H/C/000232

Product EMA number: EMEA/H/C/000232

Product short name: ReFacto AF

ATC Code: B02BD02

INN: MOROCTOCOG ALFA

MAH: Pfizer Europe MA EEIG

Generate delivery file

Reset form

Human domain only;  
Related sequence number should contain identical value to the sequence number where submission-unit is either 'Initial' or 'Reformat'.

# EV Code to be included in Product selection screen (SD-43190)

*is eCTD (mandatory  
horised (NP)  
TD please see*

EUROPEAN MEDICINES AGENCY  
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Human

Veterinary

Choose a submission type:\*

signal detection

Choose a Submission-Unit\*

initial

Mode:\*

Single Product

\*Denotes mandatory fields

Submission: signal detection

Product Type:\*

National

Submission format:\*

eCTD

Sequence number:\*

0001

Enter Epitt number:\*

23454

Select a Product(NAPs):\*

Enter product short name

✕ AFLUDITEN

MAH name	Product full name	Country...	Authorisation No....	EV Code	EMA Product/MRP/DCP...
BB PHARMA A.S.	AFLUDITEN 25 mg/ml	CZ	68/012/76-S/C	PRD1617710	
BB PHARMA A.S.	AFLUDITEN 25 mg/ml	SK	68/0012/76-S	PRD1617711	

Human domain only;  
When Nationally  
Authorised Products are  
selected for relevant  
procedures the EV Code  
is now visible in the  
Product selection screen



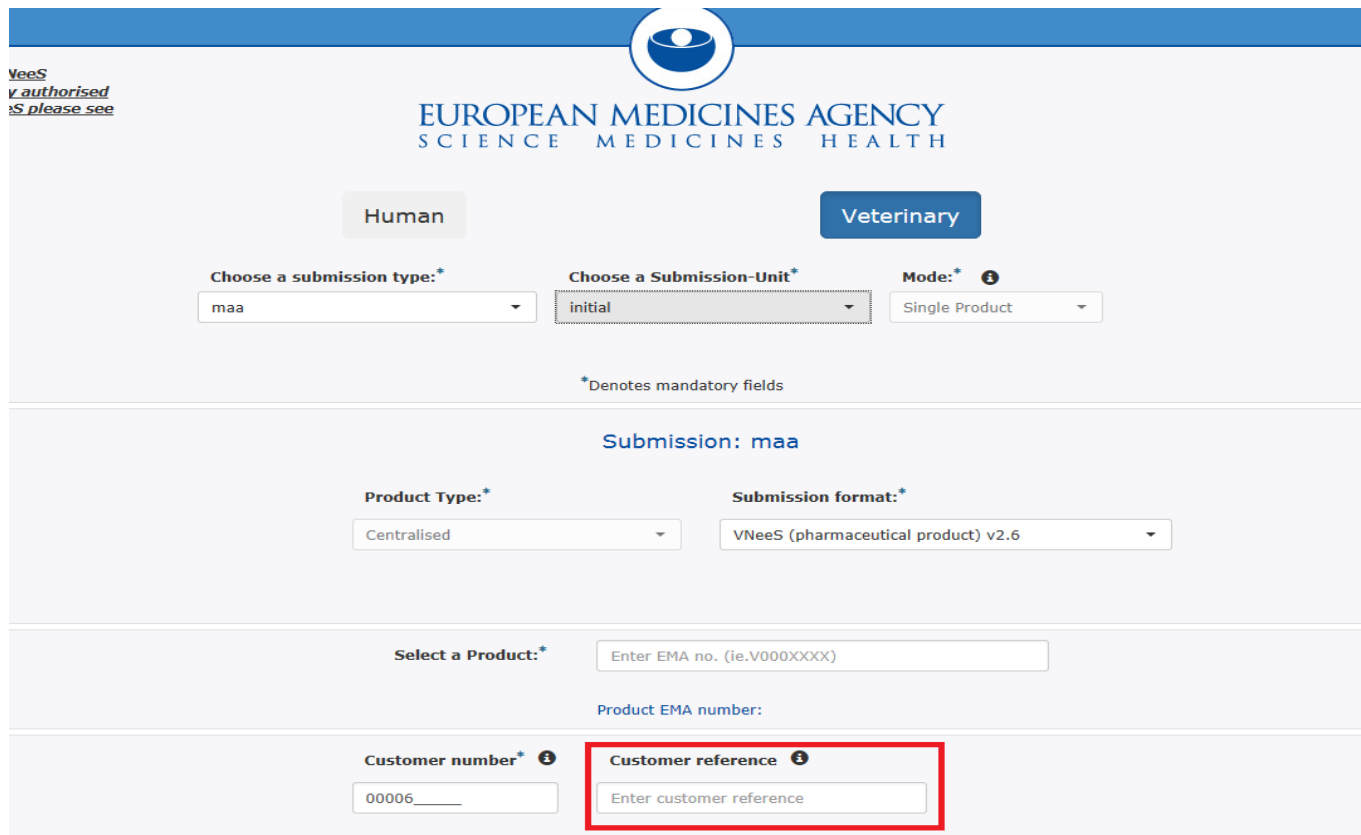
**Product selection** Procedure number: PSUSA/00000526/201806

Sequence number: \*

✓	MAH name	Product full name	Drug ingredient	Country...	Authorisation no.	EV Code	EMA product/MR...
✓	NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder and solvent for...	CANAKINUMAB	NO	EU/1/09/564/003	XXXXX	EMA/H/C/001109
✓	NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder and solvent for...	CANAKINUMAB	LI	EU/1/09/564/003	XXXXX	EMA/H/C/001109
✓	NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder for solution for...	CANAKINUMAB	LI	EU/1/09/564/001	XXXXX	EMA/H/C/001109
✓	NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg/ml solution for injection	CANAKINUMAB	IS	EU/1/09/564/004	XXXXX	EMA/H/C/001109
✓	NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg powder for solution for...	CANAKINUMAB	EU	EU/1/09/564/002	XXXXX	EMA/H/C/001109
✓	NOVARTIS EUROPHARM LIMITED	Ilaris 150 mg/ml solution for injection	CANAKINUMAB	NO	EU/1/09/564/004	XXXXX	EMA/H/C/001109
✓	NOVARTIS EUROPHARM LIMITED	Ilaris 150 ma powder and solvent for...	CANAKINUMAB	EU	EU/1/09/564/003	XXXXX	EMA/H/C/001109



Human domain only;  
 When Nationally  
 Authorised Products are  
 selected for relevant  
 procedures the EV Code  
 is now visible in the  
 Product selection screen



VeeS  
v authorised  
is please see

**EUROPEAN MEDICINES AGENCY**  
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Human **Veterinary**

Choose a submission type:\*  
maa

Choose a Submission-Unit\*  
initial

Mode:\* ⓘ  
Single Product

\*Denotes mandatory fields

Submission: maa

Product Type:\*  
Centralised

Submission format:\*  
VNees (pharmaceutical product) v2.6

Select a Product:\*  
Enter EMA no. (ie.V000XXXX)

Product EMA number:

Customer number\* ⓘ  
00006\_\_\_\_\_

**Customer reference ⓘ**  
Enter customer reference

Veterinary domain only;  
alignment of functionalities  
between human and  
veterinary domains to include  
same metadata

'Customer reference' field has  
been added for relevant  
procedures.



The screenshot shows the EMA eSubmission Web UI interface. At the top, there is a blue header with the EMA logo and the text 'EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH'. Below the header, there are two tabs: 'Human' (inactive) and 'Veterinary' (active). The 'Veterinary' tab is highlighted in blue. Below the tabs, there are three dropdown menus: 'Choose a submission type:\*' with 'transfer-ma' selected, 'Choose a Submission-Unit\*' with 'No selection' selected, and 'Mode:\*' with 'Single Product' selected. A note below these fields states '\*Denotes mandatory fields'. Below this, there is a section titled 'Submission: transfer-ma'. Underneath, there are two more dropdown menus: 'Product Type:\*' with 'Centralised' selected and 'Submission format:\*' with 'VNeES (pharmaceutical product) v2.6' selected. At the bottom, there is a 'Select a Product:\*' section with a text input field containing 'Enter product name or number'. Below the input field, there are labels for 'Product EMA number:', 'Product short name:', 'ATC Code:', 'INN:', and 'MAH:'. The 'ATC Code:', 'INN:', and 'MAH:' labels are enclosed in a red rectangular box.

Veterinary domain only;  
alignment of functionalities  
between human and  
veterinary domains to include  
same metadata

ATC code, INN and MAH  
details have been added for  
all procedure types except  
'maa'.

var-type1b initial Single Product

\*Denotes mandatory fields

**Submission: var-type1b**

**Product Type:\*** Centralised **Submission format:\*** VNeS (pharmaceutical product) v2.6

**Brexit related procedure:\***  Yes  No

**Select a Product:\*** Metacam-EMA/V/C/000033

Product EMA number: EMA/V/C/000033  
Product short name: Metacam  
ATC Code: QM01AC06  
INN: MELOXICAM  
MAH: Boehringer Ingelheim Vetmedica GmbH

**Grouping (more than one scope):**

Veterinary domain only;  
alignment of functionalities  
between human and  
veterinary domains to include  
same metadata

'Grouping (more than one  
scope)' has been added for all  
variation types.

This feature should be used  
to indicate that multiple  
scopes are affecting the same  
product – it is not the same  
as the 'IG' grouping of  
variations.

# Alignment of human and vet to include same metadata (SD-202303)

**Human** **Veterinary**

Choose a submission type:\* var-type2  
Choose a Submission-Unit\* initial  
Mode:\* WS

\*Denotes mandatory fields

Submission: var-type2

Product Type:\* Centralised  
Submission format:\* VNeES (pharmaceutical product) v2.6

Brexit related procedure:\*  Yes  No

Select a Product:\* Clomicalm-EMA/V/C/000039

Product EMA number: EMA/V/C/000039  
Product short name: Clomicalm  
ATC Code: QN06AA04  
INN: CLOMIPRAMINE HYDROCHLORIDE  
MAH: Elanco GmbH

Grouping (more than one scope):

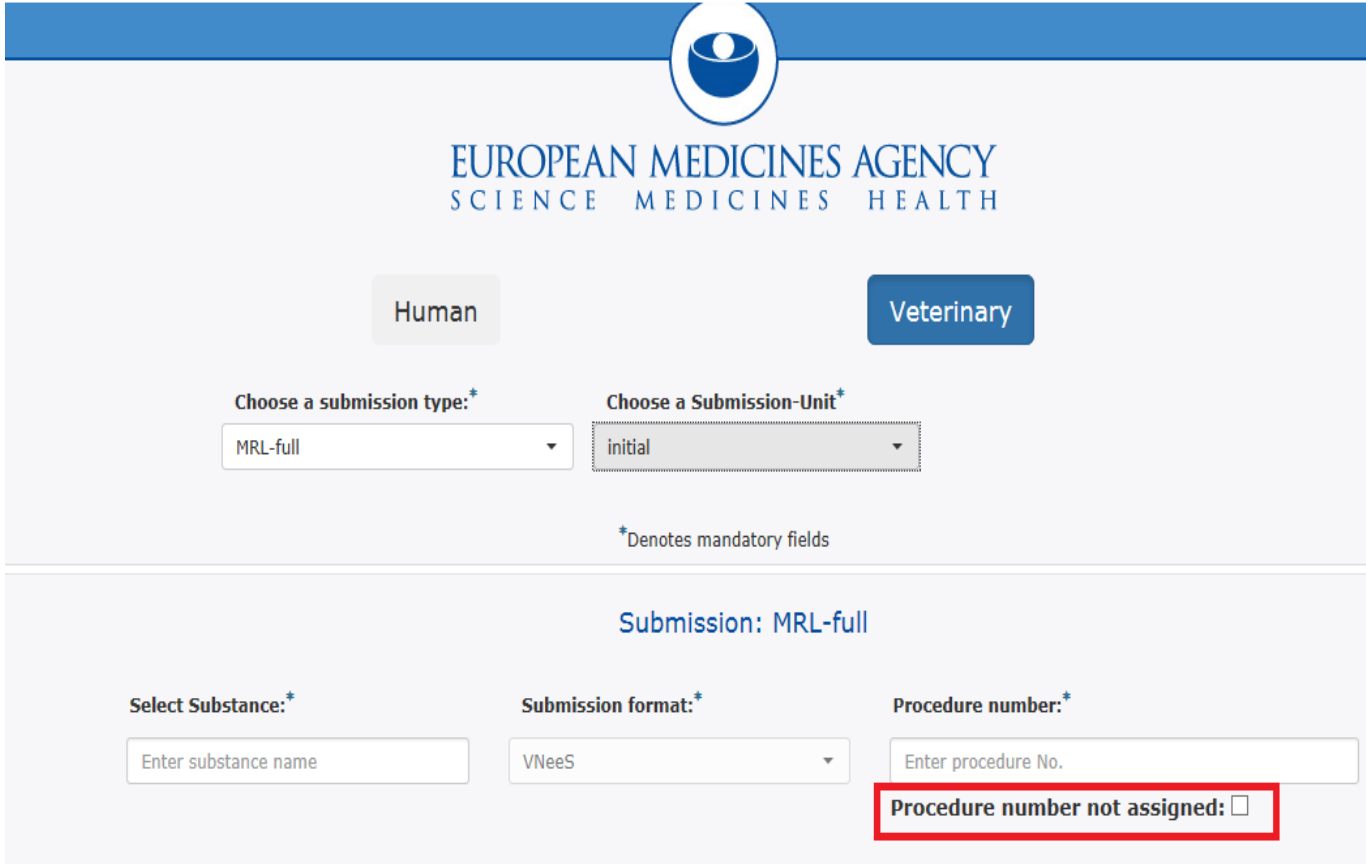
Select WS/IG number:\* Nothing selected

Customer number\* 00006  
Customer reference Enter customer reference

Veterinary domain only;  
alignment of functionalities  
between human and  
veterinary domains to include  
same metadata

For WS/IG procedures the  
same text for both Human  
and Veterinary is now used:  
'Select WS/IG number'.

For WS/IG procedures, the  
customer number and  
customer reference fields  
have been added.



Human **Veterinary**

Choose a submission type:\* MRL-full

Choose a Submission-Unit\* initial

\*Denotes mandatory fields

Submission: MRL-full

Select Substance:\* Enter substance name

Submission format:\* VNeS

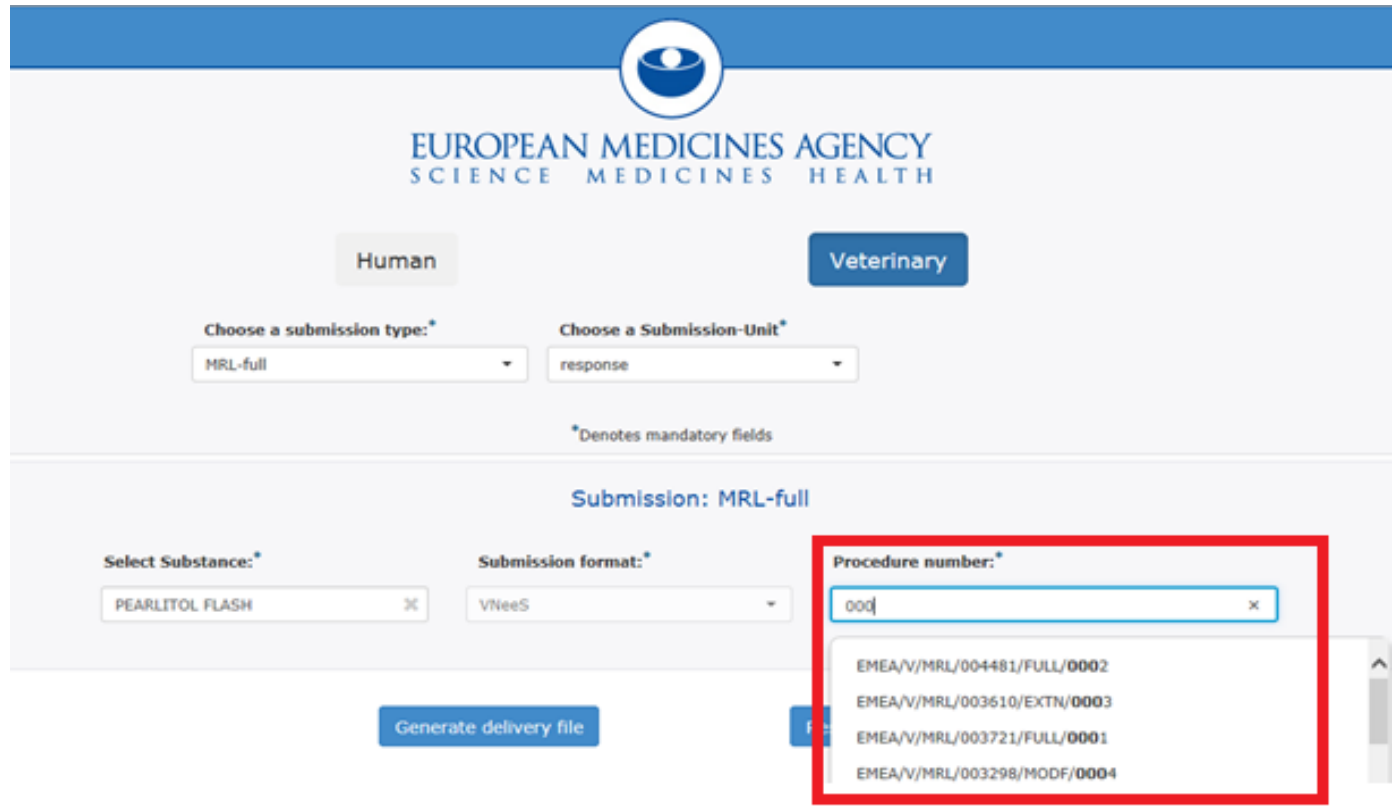
Procedure number:\* Enter procedure No.

**Procedure number not assigned:**

Veterinary domain only;  
alignment of functionalities  
between human and  
veterinary domains to include  
same metadata

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.

# Alignment of human and vet to include same metadata (SD-202303)



Human Veterinary

Choose a submission type:\* MRL-full

Choose a Submission-Unit\* response

\*Denotes mandatory fields

Submission: MRL-full

Select Substance:\* PEARLITOL FLASH

Submission format:\* VNeoS

Procedure number:\* 000

- EMEA/V/MRL/004481/FULL/0002
- EMEA/V/MRL/003610/EXTN/0003
- EMEA/V/MRL/003721/FULL/0001
- EMEA/V/MRL/003298/MODF/0004

Generate delivery file

Veterinary domain only;  
alignment of functionalities  
between human and  
veterinary domains to include  
same metadata

For MRL responses and  
additional-info the procedure  
number list shows the  
relevant MRL applications  
relating to the substance.



# Thank you for your attention

## Further information

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<https://servicedesk.ema.europa.eu>

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