EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmission Web Client v 3.7.0.0 – new functionality

Changes introduced in v3.7.0.0

09 October 2019

An agency of the European Union

Update the message on the landing page - Human (SD-198987)

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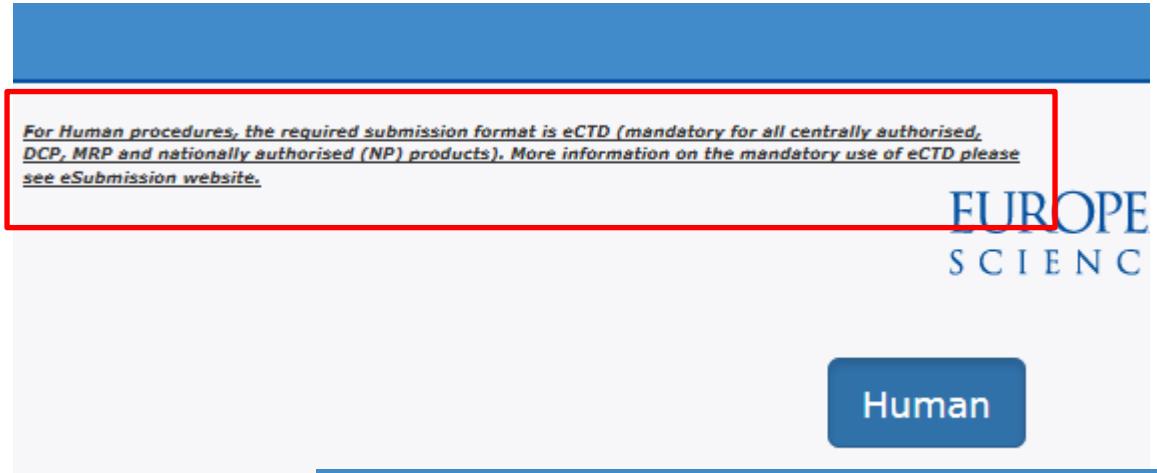
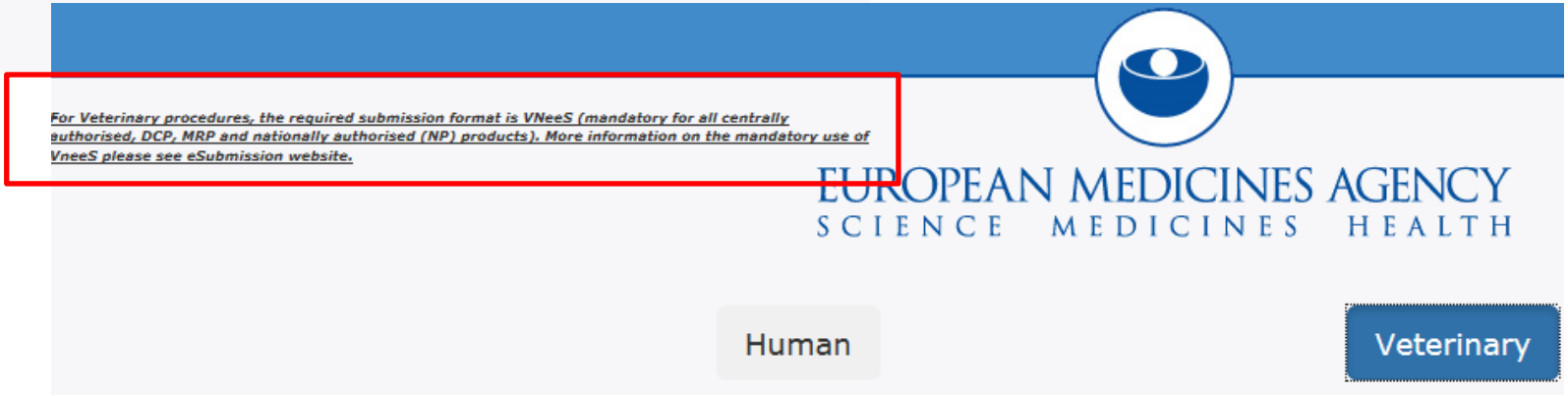
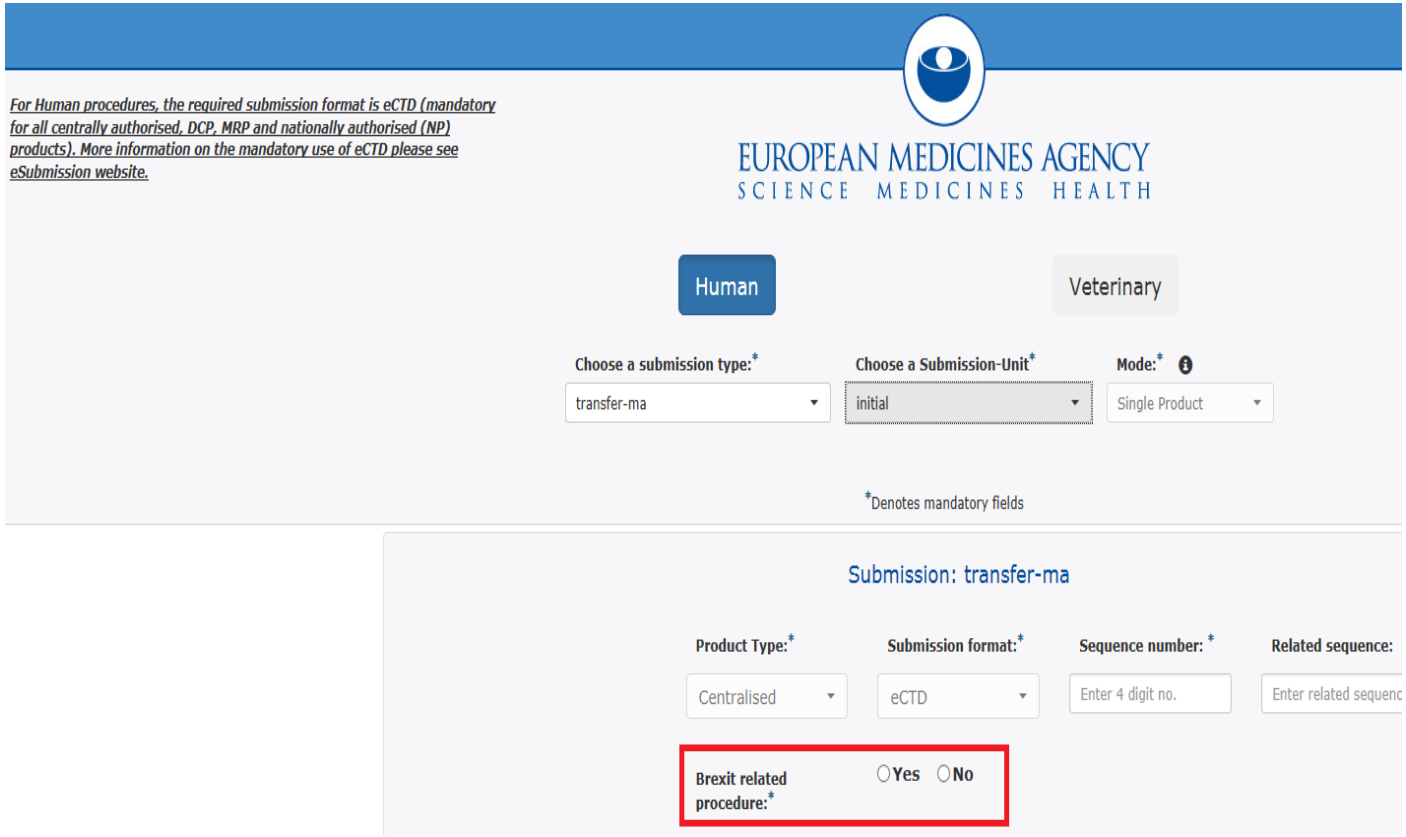




Human and Veterinary domains;

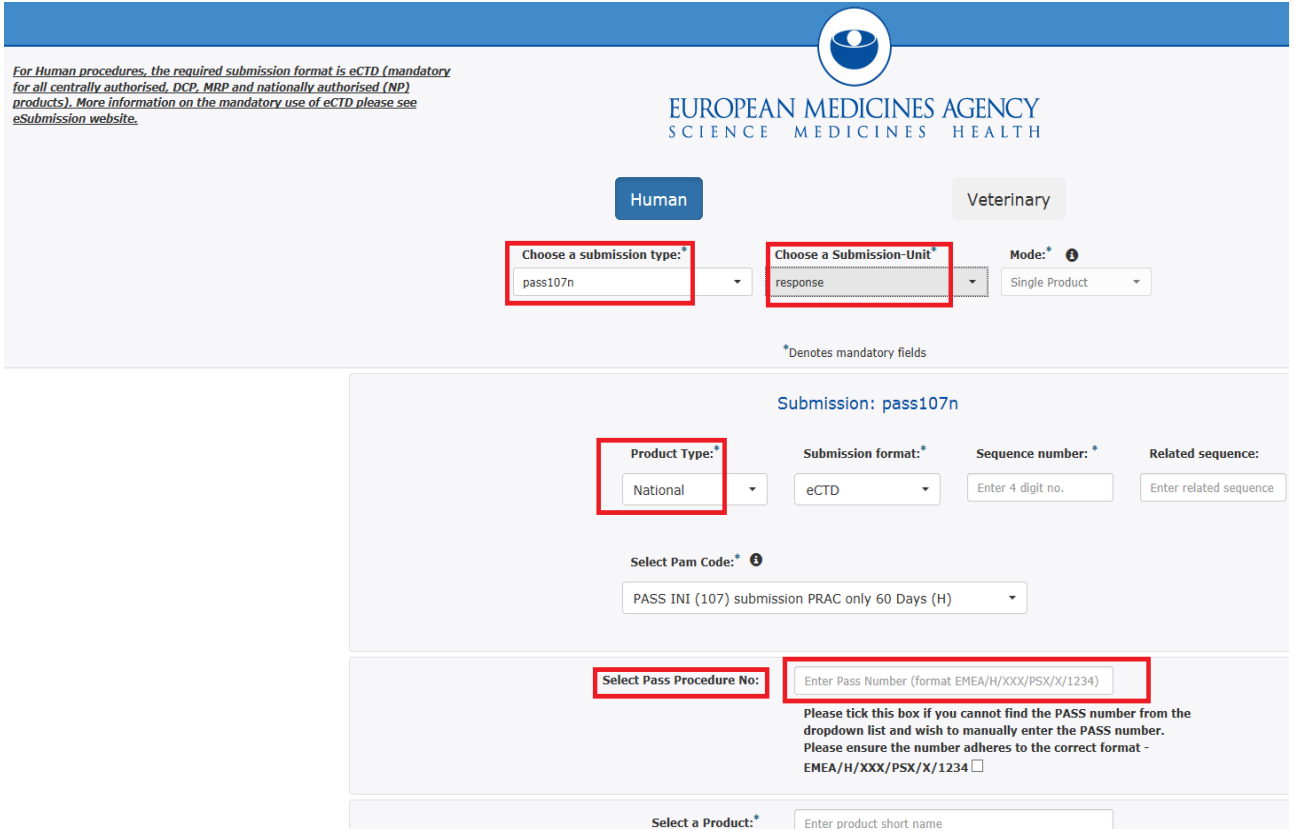
Updated message on mandatory use of eCTD/VneeS on the landing page of the Web UI for Human and Veterinary Submissions

Brexit Related Feature (SD-207332)



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

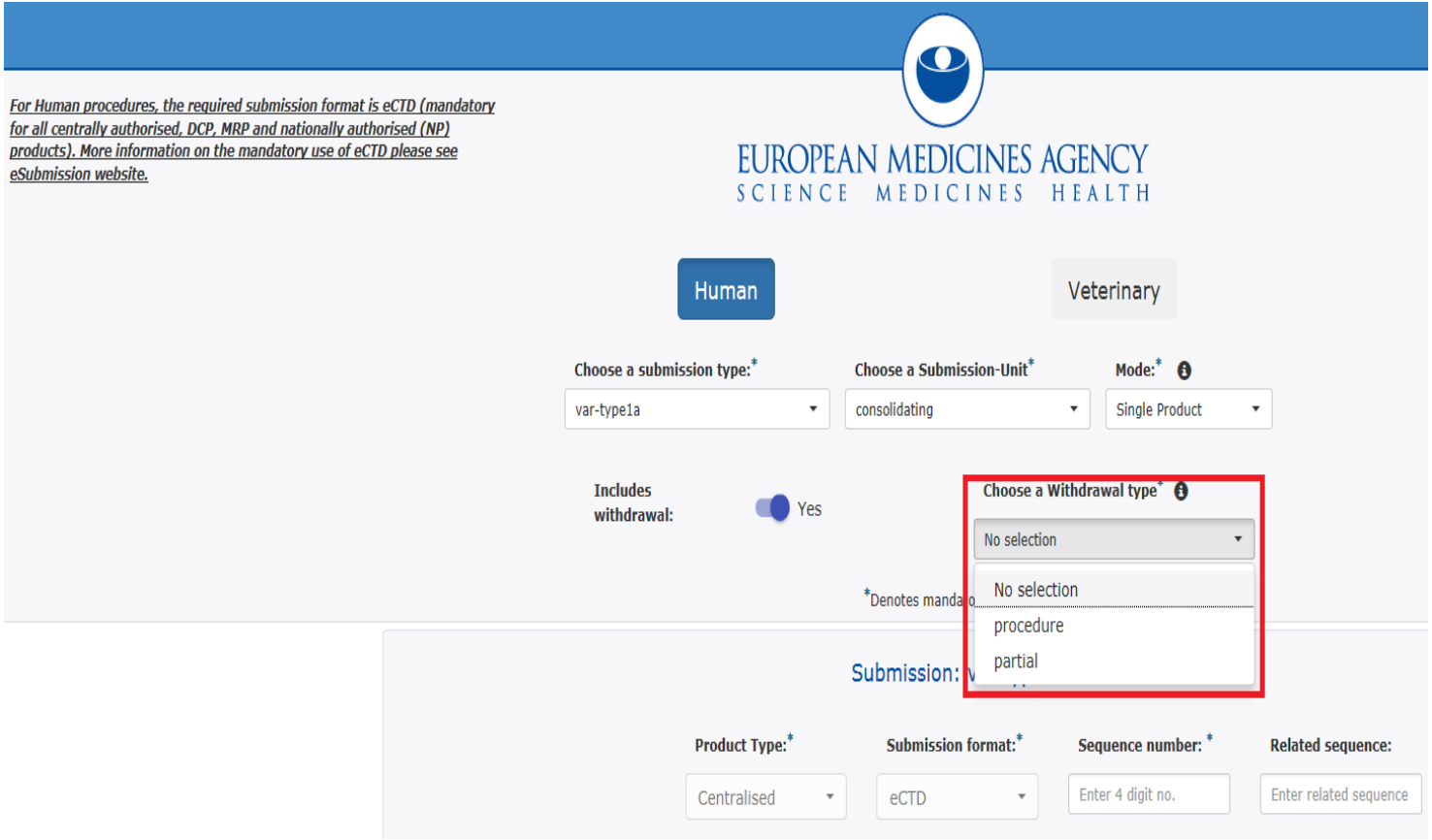
PASS 107 submission - link to PASS FM (SD-177839)



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.

Consolidation unit type – Withdrawal information (SD-198921)



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'.

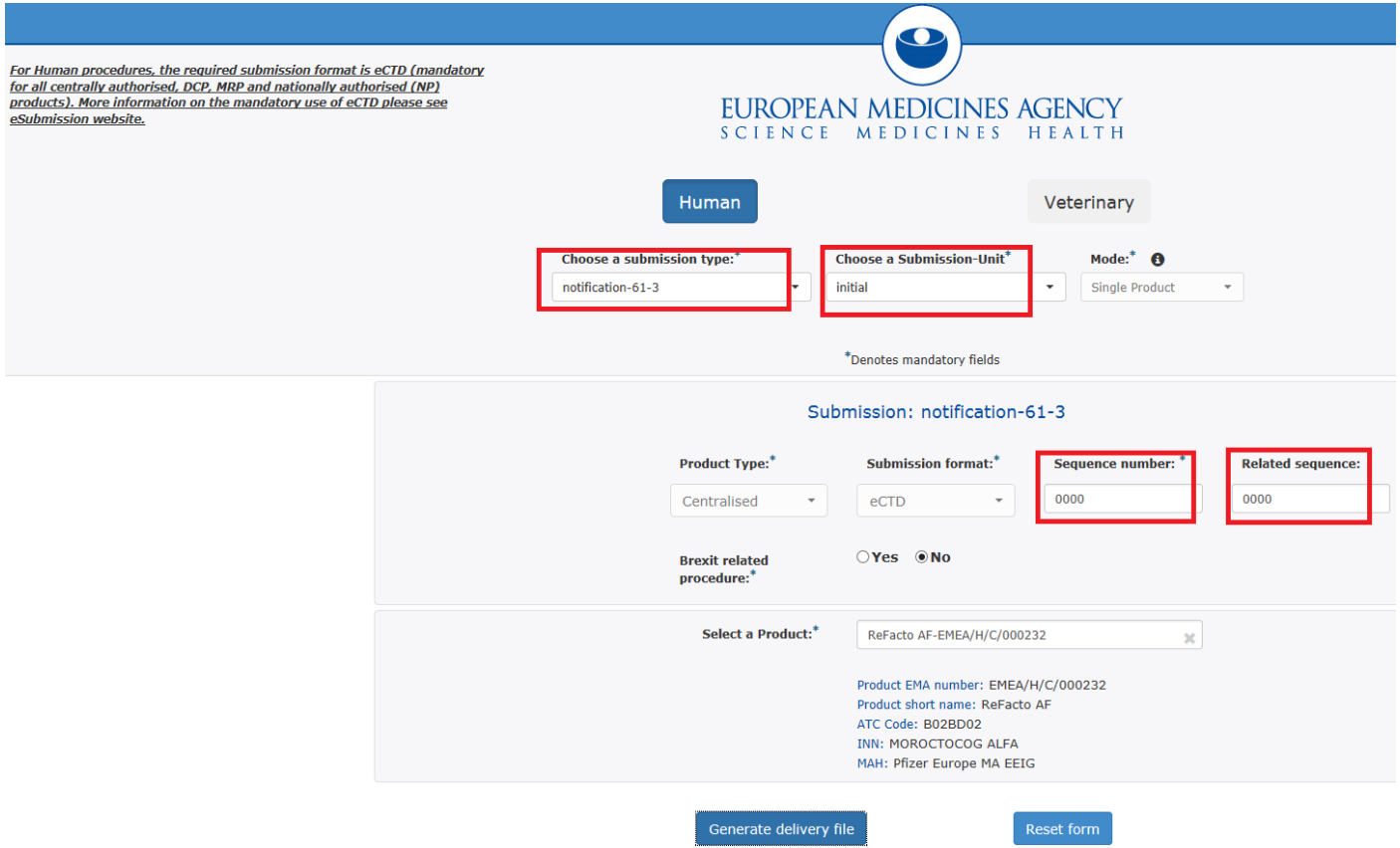
Consolidation unit type – Withdrawal information (SD-198921)

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’.

Related Sequence Number (SD-298672)



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)

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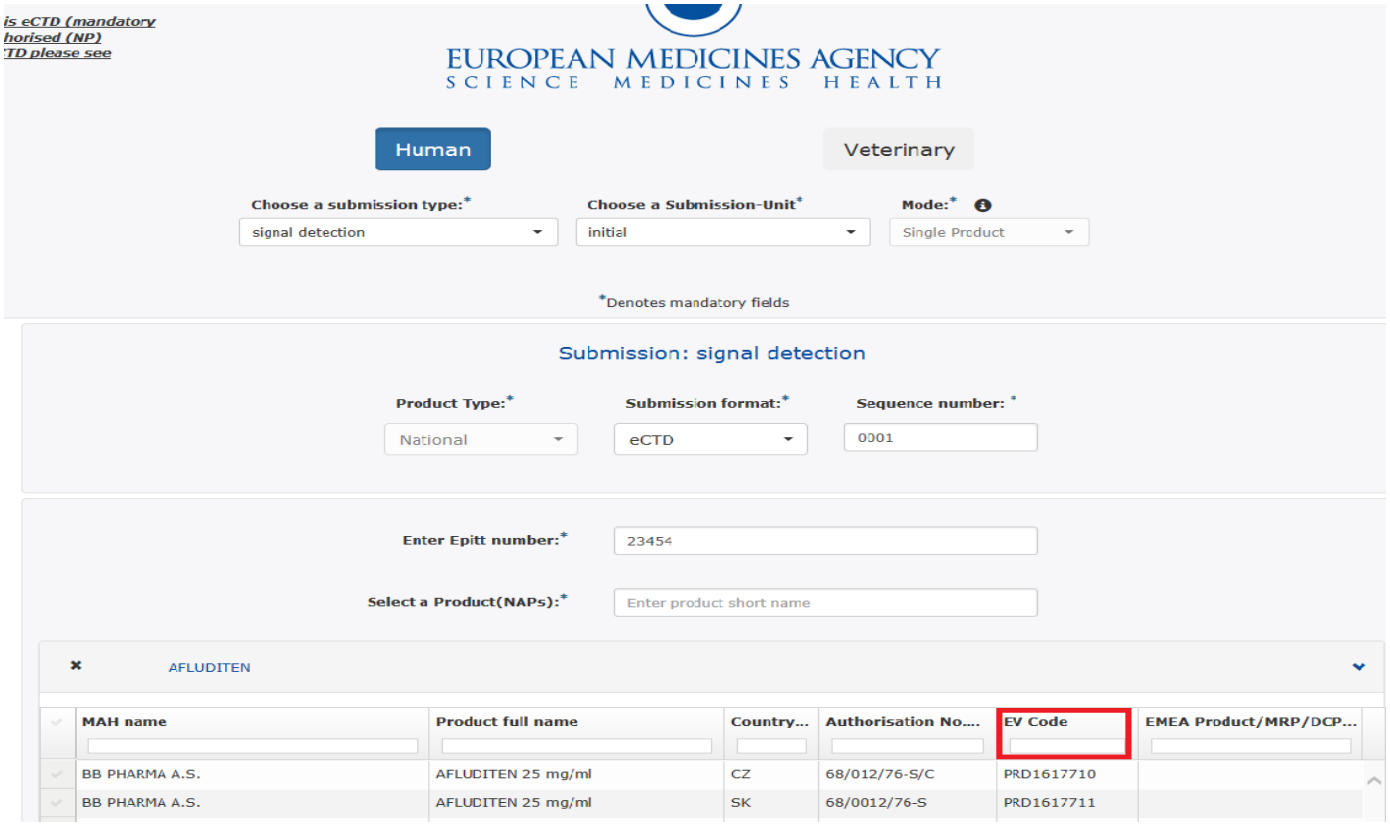
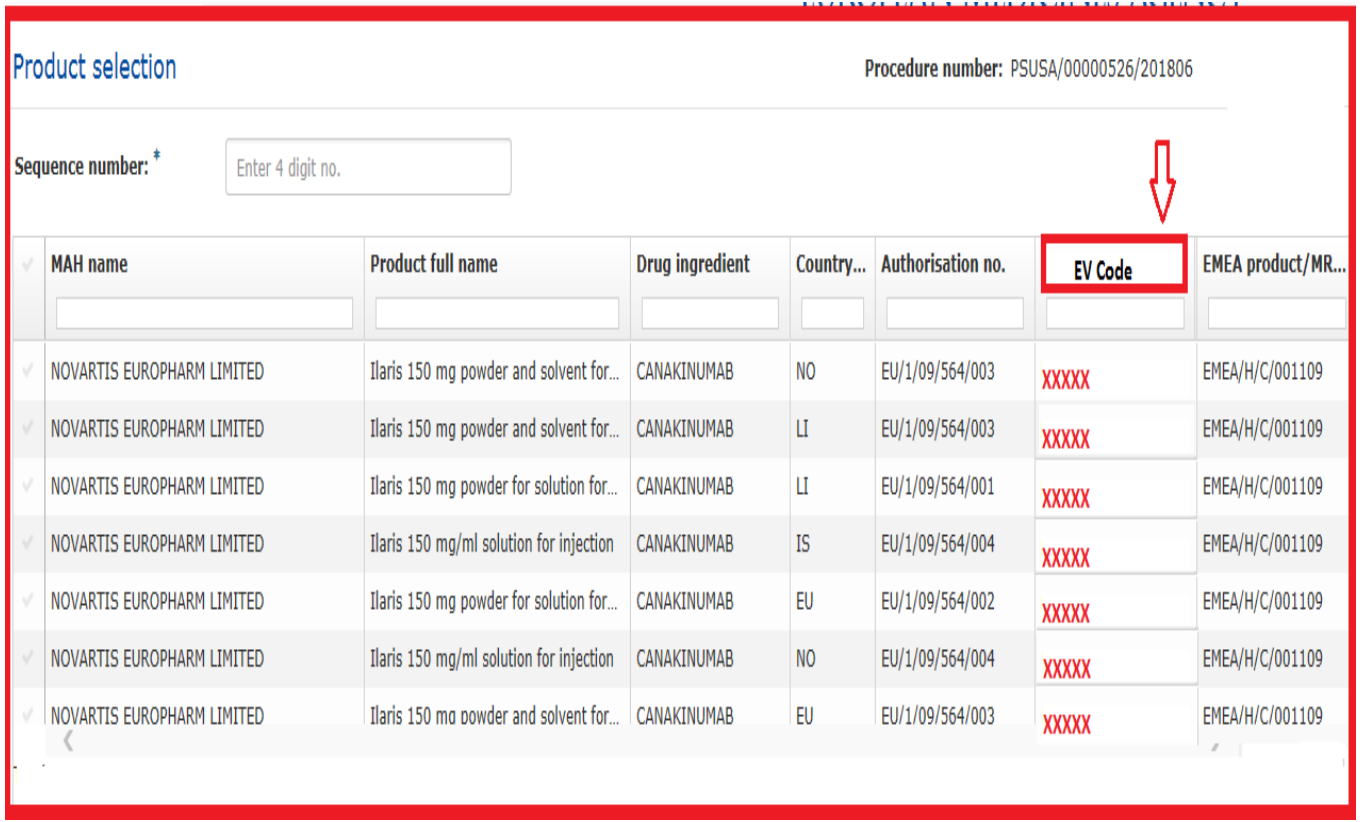


Human domain only;

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

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



Product selection

Procedure number: PSUSA/00000526/201806

Sequence number: * Enter 4 digit no.

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

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

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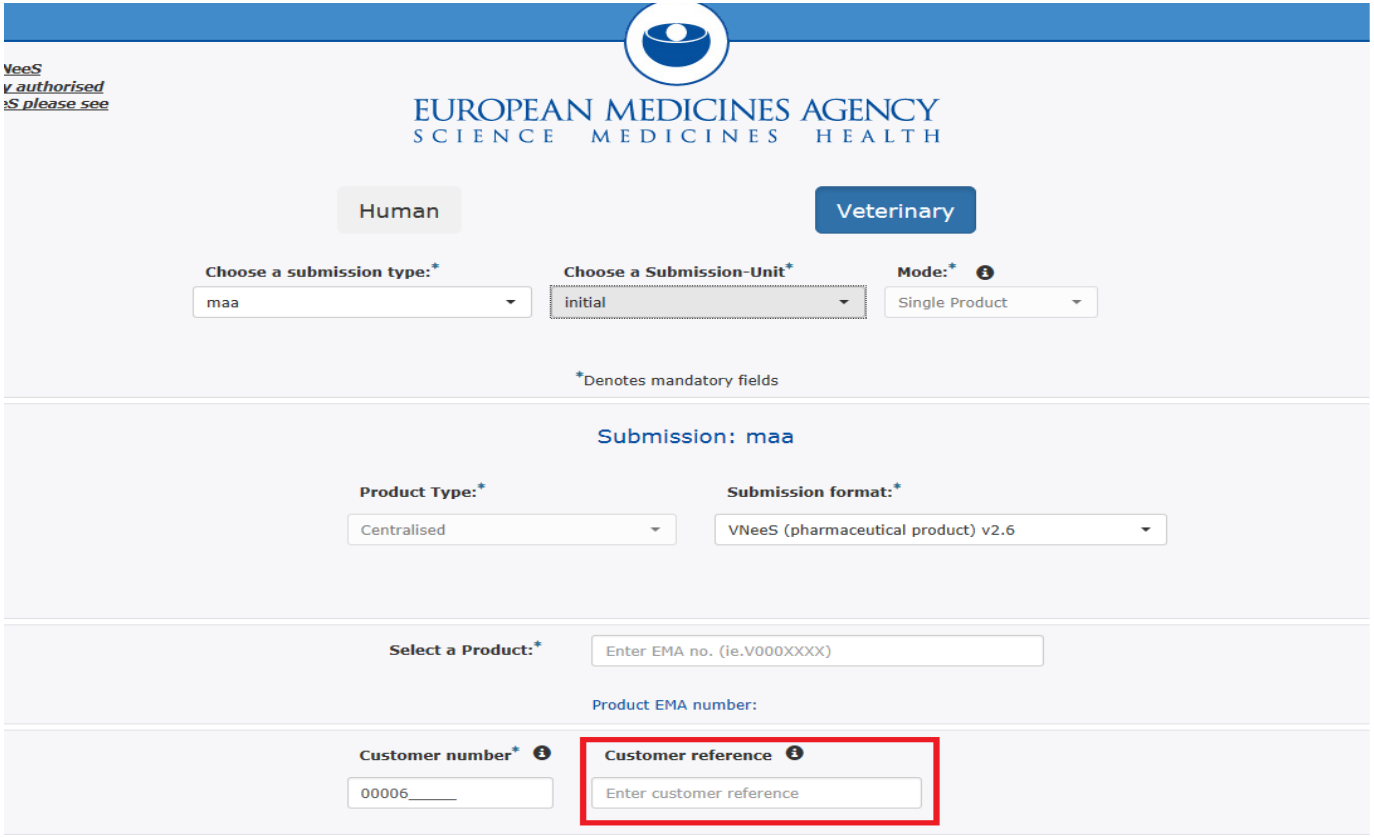

Veterinary domain only; alignment of functionalities between human and veterinary domains to include same metadata

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

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

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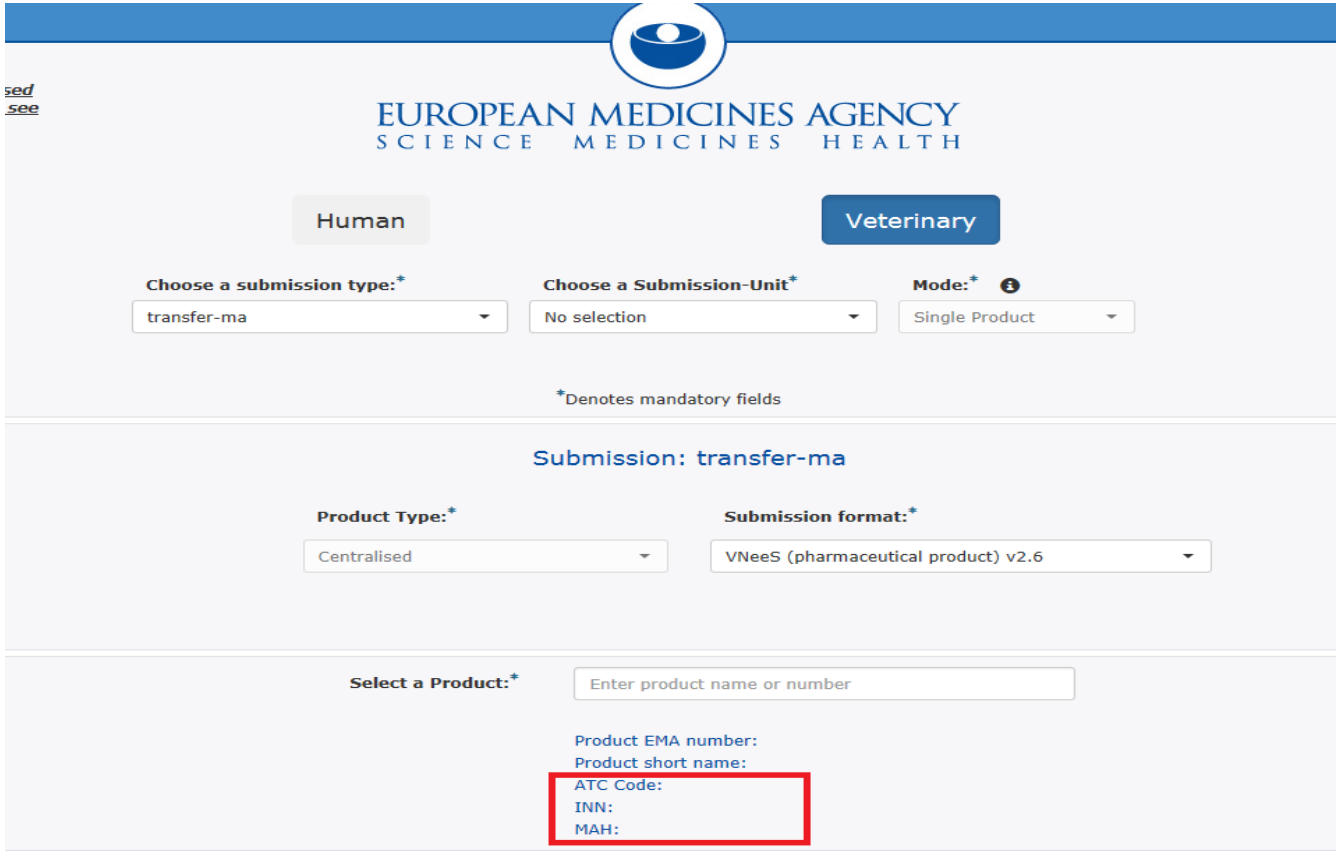
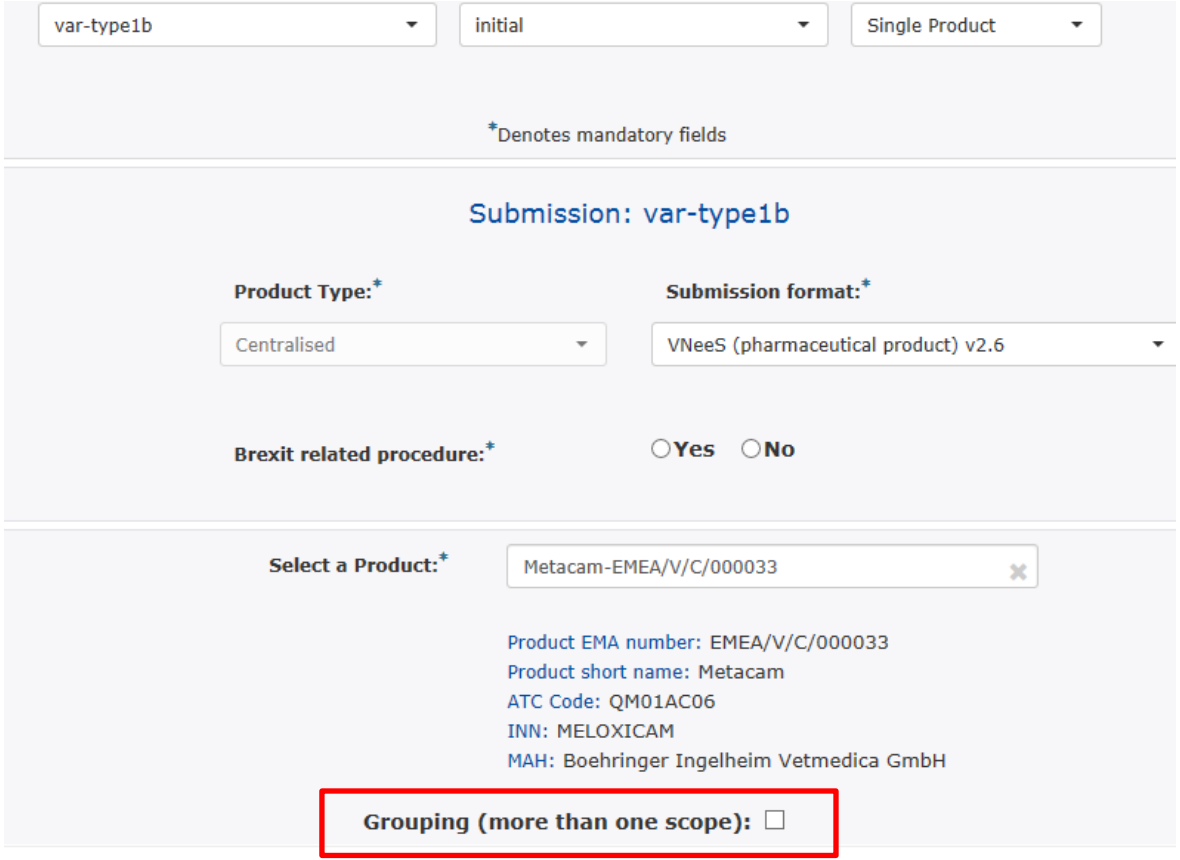


Veterinary domain only; alignment of functionalities between human and veterinary domains to include same metadata

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

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

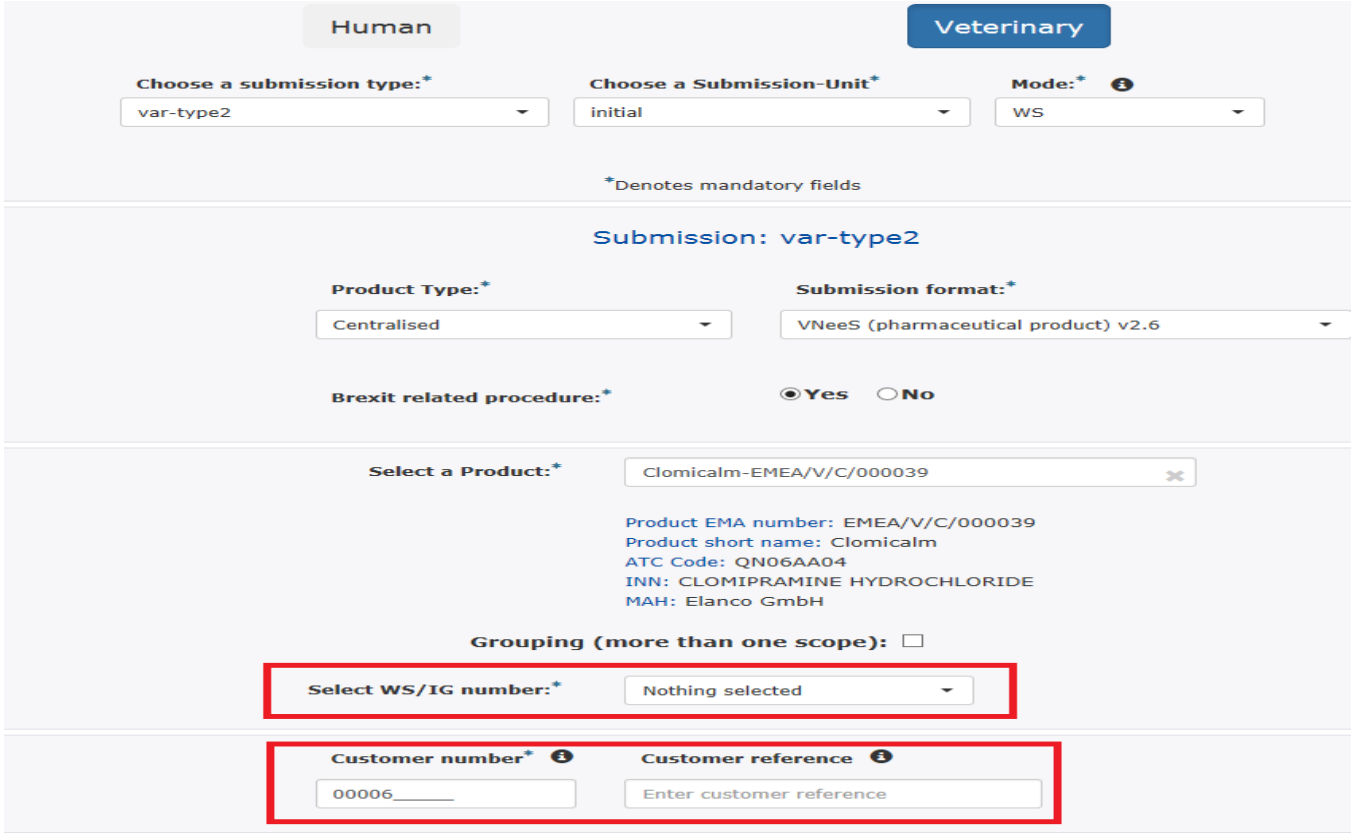


Veterinary domain only; alignment of functionalities between human and veterinary domains to include same metadata

'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)



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'.

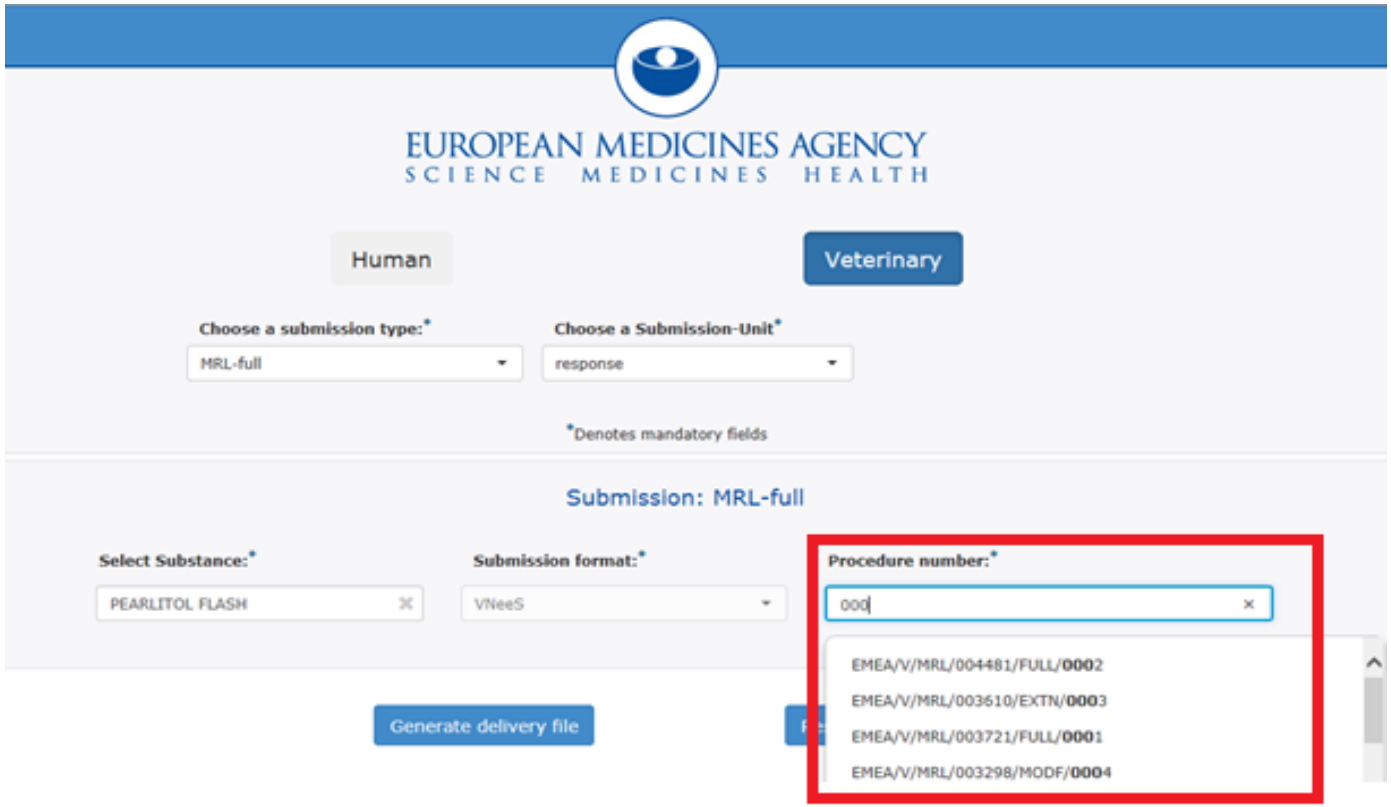
For WS/IG procedures, the customer number and customer reference fields have been added.

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

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)



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

https://servicedesk.ema.europa.eu

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