EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 March 2021
EMA/346582/2016

User Guidance for submissions via eSubmission Gateway / Web Client using xml delivery files

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Document History

Version	Date	Changes applied	Author
1.0	23/05/16	Original – documented usage of the delivery file creation functionality	Kristiina Puusaari
1.1	31/05/16	Update – ancillary medicinal substances in medical device are out of scope during the pilot phase	Kristiina Puusaari
2.0	25/07/16	Updated to reflect changes related to EU Module 1 specification v3.0.1	Kristiina Puusaari
2.1	13/10/16	Updated to clarify search for referral and ASMF procedures and update following mandatory use of EU M1 specification v3.0 and v3.0.1.	Kristiina Puusaari
2.2	02/12/16	Updated to include details of Veterinary PSUR and MRL submissions, PASS 107n, 107o and 107q submissions for Human Nationally Authorised Products and Ancillary Medicinal Products in Medical devices submissions	Kristiina Puusaari
2.3	12/12/16	Updated to reflect the change from PIP submissions to Paediatric submissions	Kristiina Puusaari
2.4	20/02/17	Updated to include guidance how to fill in additional information for Referral submissions	Kristiina Puusaari
2.5	31/03/17	Update to include guidance on using new functionality from release 3.2.0, for example the addition of new submission description field, procedure number and contact person details. See release notes for details.	Kristiina Puusaari
2.6	05/05/17	Update from release 3.2.0 RC4 to reflect changes to contact person contact details	Kristiina Puusaari
2.7	27/06/17	Update from Release 3.2.2 to reflect changes to the user interface e.g. changes to clinical trial publication, rmp and ancillary medicinal product submissions. See release notes for details.	Kristiina Puusaari
2.8	01/09/17	Update from Release 3.2.3.0 to reflect change to the user interface e.g. addition of the 'pam' code list to pam (all but capa) and pass 107n, p and q submissions	Kristiina Puusaari
2.9	29/09/17	Update from Release 3.3.0.0 to reflect change to the user interface for veterinary submissions e.g. addition of submission description, change of submission format field to provide information on the product and	

Version	Date	Changes applied	Author
2.10	28/02/18	Updated to reflect changes introduced in v3.4.	Asim Qureshi
2.11	05/07/18	Updated to reflect changes introduced in v3.5	Sandeep Senguttuvan
2.12	19/09/18	Updated to reflect changes implemented in release v3.6	Asim Qureshi
2.13	07/10/19	Updated to reflect changes implemented in release v3.7 and general updates	Kristiina Puusaari
2.14	04/11/19	Updated to reflect changes implemented in release v3.7.0.1	Kristiina Puusaari
2.15	27/02/20	Updated to reflect changes implemented in release v3.7.0.3	Kristiina Puusaari
2.16	05/05/20	Updated to reflect addition of 'Covid-19' related flag as implemented in release v3.7.0.5	Kristiina Puusaari
2.17	24/06/20	Updated to reflect the change in the label from 'is this ancillary device' to 'Medical Device Related Consultation'	Kristiina Puusaari
2.18	19/11/20	Updated to reflect the changes introduced in release v3.7.3.0 (major changes in paediatric submissions and other changes as per detailed in the release notes)	Kristiina Puusaari
2.19	08/03/21	Updated to reflect changes introduced in releases v3.7.5.0 (changes in the Veterinary domain for MRL and referral submissions as detailed in the release notes)	Kristiina Puusaari
2.20	11/03/21	Updated to reflect changes introduced in releases v3.7.6.0 (Customer reference has been renamed to Purchase Order Number, addition of new nitrosamine related radio button for human variations as detailed in the release notes). Addition of details for EPITT signal detection submissions.	Kristiina Puusaari

1. Introduction

This document serves as a simple guide for applicants to submit applications via the eSubmission Gateway / Web Client using xml delivery files. It highlights the restrictions and conventions that users need to be aware of when generating submission and delivery files.

It also describes the existing constraints and workaround solutions to enable submissions to the agency.

The document assumes prior knowledge of the eSubmission gateway processes and will therefore focus on the process of creating delivery files to be included in the submissions.

Communication regarding the introduction of the xml delivery files for the submission process can be found from the eSubmission website.

2. Scope of the eSubmission Gateway xml delivery file system

The use of xml delivery files is mandatory for all human (including Paediatric submissions) and veterinary domain submissions to EMA for which the relevant delivery files are available. Use of filenaming conventions is no longer allowed. Use of the xml delivery files requires inclusion of the delivery file in the submission package. When the **xml delivery file** is **included** in the package, **the filenaming conventions are no longer checked** and a simple, meaningful name should be given to the submission zip folder.

There is an intention to integrate the Formatted Table Template into the XML delivery file and number of fields familiar from the formatted table template should now be filled in in the XML delivery file user interface. This is the first phase of the integration of the new fields into the XML delivery file and it does not affect the use of the Formatted Table Template.

The xml delivery files can currently be used for the following **submission types**:

Human

Submission Type	Description
annual-reassessment	Annual Re-assessment
clin-data-pub-fv	Clinical data for publication – Final version
clin-data-pub-rp	Clinical data for publication – Redacted Proposal
extension	Extension
lifting-suspension	Lifting of suspension
maa	Marketing Authorisation Application
notification-61-3	Notification Art. 61(3)
pam-anx	Condition of a marketing authorisation granted for a medicinal product, listed in Annex II of the MA
pam-capa	Corrective Action/Preventative Action related to a post-authorisation measure

pam-leg	Legally binding measure related to a post-authorisation measures
pam-mea	Additional pharmacovigilance activity in the risk-management plan related to a post-authorisation measure (RMP) (e.g. interim results of imposed/non-imposed interventional/non-interventional clinical or non-clinical studies)
pam-p46	Paediatric submissions related to a post-authorisation measure
pam-paes	Submission of post-authorisation efficacy study
pam-rec	Recommendation related to a post-authorisation measures e.g. quality improvement related to a post-authorisation measure
pam-sda	Cumulative review following a request originating from a PSUR or a signal evaluation related to a post-authorisation measure
pam-sob	Specific obligation related to a post-authorisation measure
pass107n	Submission of a post authorisation safety study protocol (according article 107n) – NAPs
Pass107o	Submission of an amended post authorisation safety study protocol (according article 107o) – CAPs and NAPs
pass107q	Submission of a post authorisation safety study report (according article 107q) – NAPs
reformat/baseline	Reformat of dossier*
renewal	Renewal
rmp	Risk Management Plan (RMP)
transfer-ma	Transfer of a marketing authorisation
usr	Urgent Safety Restriction (USR)
var-type1a	Type IA variation (single and IG)
var-type1ain	Type IA_{IN} variation (single and IG)
var-type1b	Type IB variation (single and WS)
var-type2	Type II variation (single and WS)
withdrawal	Withdrawal
Referrals	
• Article5(3)	Referral under Article 5(3)
• Article13	Referral under Article 13
• Article16C1C	Referral under Article 16c (1c)i
• Article16C4	Referral under Article 16c(4)
• Article20	Referral under Article 20
• Article29(4)	Referral under Article 29(4)

• Article30	Referral under Article 30
• Article31	Referral under Article 31
• Article35	Referral under Article 35
• Article107i	Referral under Article 107i
• Article29PAED	Referral under Article 29 paediatric
asmf	Active Substance Master File (ASMF)
pmf	Plasma Master File (PMF)
article-58-WHO	Periodic Safety Update Report (PSUR) which should only be used for products authorised under Art. 58 (WHO)
psur/psusa	Periodic Safety Update Report (PSUR) which should only be used for PSURs outside of the PSUSA / PSUR single assessment procedure. This selection will take the user automatically to the PSUR Repository user interface.
Paediatric Submission Available Procedure types; • Annual Report • Class-waiver confirmation request • Compliance check • Condition/indication confirmation request • Discontinuation • Modification of an agreed PIP • Paediatric Investigation Plan • Waiver	Paediatric submissions (should be used for all paediatric submissions e.g. pips, modifications, waivers, responses, requests for modification, requests for compliance checks and annual reports and deferrals)
signal detection	Signal Detection submissions for Nationally Authorised Products (NAPs) with EPITT number

***** In the exceptional case of reformatting the application no regulatory activity (submission type) is allowed. Therefore, 'none' must be stated (in the eCTD envelope). The submission application unit will identify the sub-activity related to the product. In the submission description some information can be provided to e.g. highlight specific modules being reformatted. The delivery file user interface will show value 'none' as reformat/baseline for usability reasons. The eCTD envelope should contain value 'none'.

Veterinary

Submission Type	**Description**
annual-reassessment	Annual Re-assessment
article-45	Procedure under Article 45 of Regulation (EC) No 726/2004, initiated by the European Commission and Member States in parallel to a referral for products of the same active substance or

	therapeutic class, for veterinary medicinal products authorised through the centralised procedure which cannot be included in referral procedures
extension	Extension
lifting-suspension	Lifting of suspension
maa	Marketing Authorisation Application
pam-anx	Condition of a marketing authorisation granted for a medicinal product, listed in Annex II of the MA
pam-leg	Legal requirement related to an authorised medicinal product
pam-mea	Additional pharmacovigilance activity in the risk-management plan (RMP) related to an authorised medicinal product (e.g. interim results of imposed/non-imposed interventional/non-interventional clinical or non-clinical studies)
pam-rec	Recommendation related to an authorised medicinal product (e.g. quality improvement)
pam-sda	Cumulative review following a request originating from a PSUR or a signal evaluation related to a medicinal product
pam-sob	Specific obligation related to an authorised medicinal product
pass	Post-authorisation safety study
reformat/baseline	Reformat of dossier taking place outside of any regulatory procedure
renewal	Renewal
rmp	Risk Management Plan (RMP)
transfer-ma	Transfer of a marketing authorisation
var-type1a	Type IA variation (single and IG)
var-type1ain	Type IA_{IN} variation (single and IG)
var-type1b	Type IB variation (single and WS)
var-type2	Type II variation (single and WS)
withdrawal	Withdrawal of a marketing authorisation in full or in part
referrals	
• Article13	Referral under Article 13 of Regulation (EC) No 1234/2008
• Article30(3)	Referral under Article 30(3) Regulation (EC) No 726/2004
• Article33(4)	Referral under Article 33(4) of Directive 2001/82/EC
• Article34	Referral under Article 34 of Directive 2001/82/EC
• Article35	Referral under Article 35 of Directive 2001/82/EC

• Article78	Referral under Article 78 of Directive 2001/82/EC
mrl-extension	Extension of a Maximum Residue Limit
mrl-extrapolation	Extrapolation of a Maximum Residue Limit
mrl-full	Full Maximum Residue Limit application
mrl-modification	Modification of a Maximum Residue Limit
asmf	Active Substance Master File (ASMF)
vet-psur	PSURs for veterinary products

The **submission-unit** is an attribute introduced in the EU Module 1 Specification v.3.0. The concept of submission unit has been additionally implemented for veterinary submissions for reasons above, even though these are not submitted in eCTD format.

The following submission unit values may be used:

initial	Initial submission to start any regulatory activity
validation-response	For rectifying business validation issues
response	Submission unit type that contains the response to any kind of question*, out-standing information requested by the agency * Use this unit for responses to Lists of Questions and Lists of Outstanding Issues, Requests for Supplementary Information, etc.
additional-info	Other additional information (could include, for example, missing files) and should only be used, if validation-response or response is not suitable
closing	Submission unit type that provides the final documents in the centralised procedure following the decision of the European Commission
consolidating	This submission unit type should also be used when consolidating the dossier in as a result of withdrawing or rejecting a single regulatory activity (not in case of the withdrawal of the entire application/marketing authorisation). This submission unit is not available for veterinary submissions.
Corrigendum	Correction to the published annexes in the centralised procedure (usually shortly after approval)
reformat	Intended to support the reformatting of an existing submission application from any format to eCTD*, i.e. a baseline eCTD submission containing no content change and which will not be subject to review (see example below). This type will always be used together with the submission type 'none' * For veterinary submission the reformat may apply to historical non-VneeS dossiers which need to be converted to VneeS format. In the exceptional case of reformatting the application no regulatory activity (submission type) is allowed. Therefore, 'none' must be stated. The submission unit will identify the sub-activity related to the product. In the submission description some information can be provided to e.g.

	highlight specific modules being reformatted. The delivery file user interface will show value 'none' as reformat/baseline for usability reasons. The eCTD envelope should contain value 'none' for submission type and 'reformat' for submission unit.

The **submission description** is an attribute introduced in the XML delivery file to provide more details on the type of response provided.

The following submission description values may be used for both, human and veterinary submissions:

Responses to RSI	Responses for Request for supplementary information used for all post-authorisation activities (automatically selected for relevant post-authorisation submissions).
List of Questions	Response to List of Questions (MAA or extension only)
List of Outstanding Issues	Response to List of Outstanding Issues (MAA or extension only)
After provisional MRL	New submission description to be used for MRL submissions only

The **submission-units for paediatric submissions** are different from those introduced in the eCTD EU Module 1 Specification v.3.0. The concept of submission unit has been additionally implemented for **paediatric** submissions to provide further information to improve searchability in the Common Repository and to assist processing of the applications, even though these are not submitted in eCTD format.

The following submission unit values may be used:

Additional information	When invited, to provide a response to the PDCO's discussion for certain procedure types. This submission unit is to be used in conjunction with additional submission descriptions detailed below.
Answer to PDCO's request for information	To respond to PDCO's request for additional information on a waiver application
Answer to PDCO's request for modification	To respond to PDCO's request for modification of a PIP (at Day 60)
Notification of change	To Inform the EMA of any changes to the applicant or their contact details. This submission unit is to be used in conjunction with additional submission descriptions detailed below * Use this unit for notifications of change; for example, change of the applicant or in the contact person etc.
Pre-submission interaction	To request a pre-submission interaction
Re-examination	To request a re-examination of a PDCO opinion on a PIP, Waiver or Modification of an agreed PIP procedure
Request for clarification interaction	To request a clarification interaction for PIP during clock-stop
Revocation	To request a revocation of waiver
Submission (application)	Initial submission to apply for a paediatric procedure

validation-response	To respond to validation issues
Withdrawal	To request a procedure withdrawal

The **submission descriptions for Paediatric submissions** are attributes introduced in the XML delivery file to provide more details on the type of paediatric submission provided.

The following submission description values may be used for paediatric submissions only:

Applicant change due to take-over by new legal entity	Use this submission description to inform EMA of a change of any of the applicant / EMA decision addressee. Use the first one listed in this table if more than one category applies.
Applicant particulars' change	Use this submission description to inform EMA of a change of the applicant's particulars for example change of the address of the applicant. Use the first one listed in this table if more than one category applies.
Authorised contact person change	Use this submission description to inform EMA of a change of the contact person (change of name, email address, phone number). Use the first one listed in this table if more than one category applies.
Public enquiry contact change	Use this submission description to inform EMA of a change of a change of the public enquiry contact person. Use the first one listed in this table if more than one category applies.
Response to Day 30 PDCO discussion	Provide Additional Information as a Response to PDCO discussion at Day 30
Response to Day 90 PDCO discussion	Provide Additional Information as a Response to PDCO discussion at day 90

3. The submission process

Submission via the eSubmission Gateway using xml delivery files is a 2 step task:

1 Create a delivery file for your submission by navigating to the eSubmission website XML delivery file preparation screen. The link to the delivery file creation screen is available on the navigation panel on the left hand side of the screen. See Create delivery file screen section.

2 Add the delivery file to the top-level folder of your document package and submit this document package via eSubmissions Gateway / Web Client. See eSubmission Gateway website for detailed guidance on how to register and how to use the eSubmission Gateway and the Web Client.

Note: The filenaming conventions are no longer used and **cannot** be **validated** when a **delivery file** is **included** in the submission and hence a **simple, meaningful** filename may be given to the submission package when delivery files are used. It is important to note that special characters or dash (-) should not be used in filenames.

Important note:

If submission covers any **duplicate** products, groupings or worksharing submissions a **separate delivery file needs to be created and attached to each submission.** For example: you are submitting a worksharing variation application for product A and product B which are both managed using a **separate** eCTD product lifecycles. A separate submission is required for **each product** to ensure continuity of the eCTD lifecycle and a separate delivery file and a separate submission must be prepared for both products.

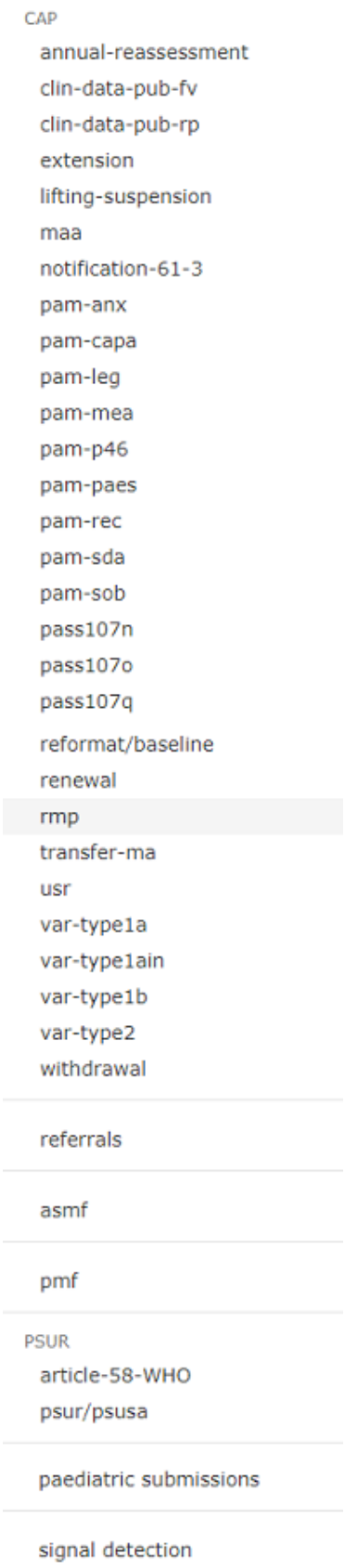
The above requirement does not apply to veterinary (VneeS) grouping, worksharing, referral and PSUR submissions.

4. Create delivery file screen – Centralised Procedure including Medical Devices

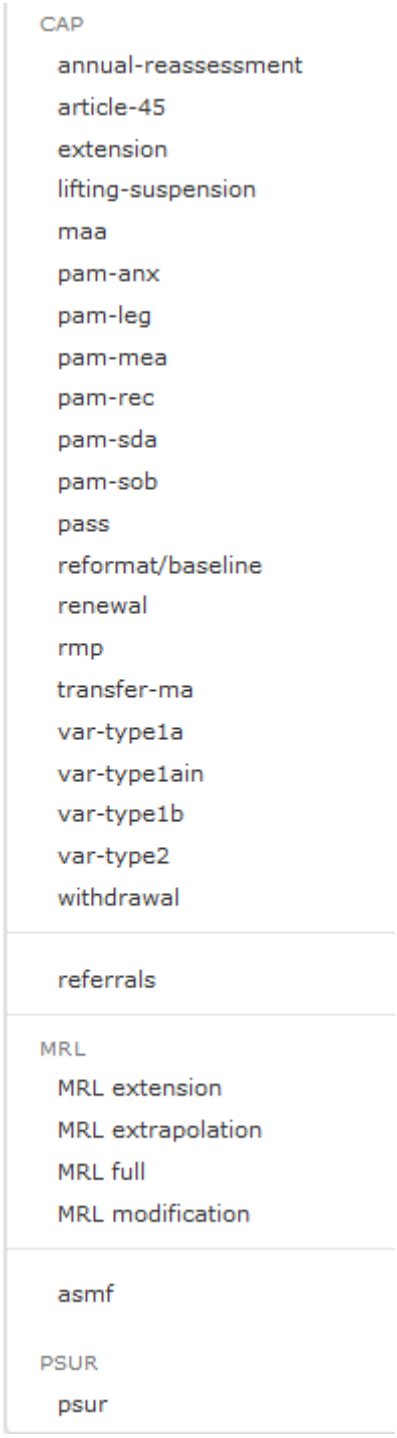
Each delivery file that is generated will have a unique name consisting of word 'delivery' with 9 or 10 digit number, for example 'delivery_435108440'. The delivery file can be renamed, however it must contain word 'delivery' as the first word and special or non-latin characters must not be used as these may lead to failure of the submission.

The user will be required to complete all mandatory fields in each section. Ensure you always **first** select the appropriate domain for your submission (**human** or **veterinary**). This will determine which options are required to be selected for the given type of submission.

Example: Human submission types

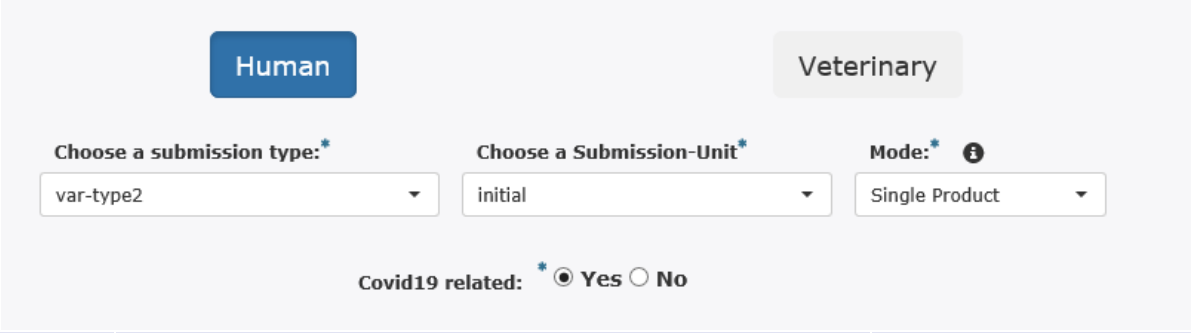


Example: Veterinary submission types



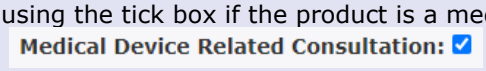
4.1. Create delivery file

Step	Description	Notes
1	**Human submissions:** Select regulatory activity from the list provided under the "Choose a submissions type" heading. The regulatory activities available reflect the updated EU M1 3.0.3. **Veterinary submissions:** Click on the 'Veterinary' button to enter the veterinary submissions domain. Select regulatory activity from the list provided under the "Choose a submissions type" heading. This will call out a set of further fields appropriate for completion for that submission type. The regulatory activities available cover procedure types handled by the EMA. All veterinary submissions, including Maximum Residue Limit (MRL) and veterinary PSUR submissions should be sent using the xml delivery file.	**Additional submission types**, outside the EU M1 specification, **covering EMA business processes are listed under submission type.**
2	**Submission unit:** Select the relevant 'Submission-Unit' for your submission.	Submission unit type describes the content at a lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity.
3	**Submission description** For Centralised Procedure submissions, when submission-unit 'Response' is selected the attribute **submission description** should be selected for extension and MAA applications. This mandatory field will provide further details on the type of response selected. The user should select List of Questions or List of Outstanding Issues as relevant. When submission unit consolidation is selected, it is possible to indicate if the procedure includes a withdrawal. For extension and variation procedures it is possible to indicate if the withdrawal is for partial or for the whole procedure. For all other submission types option 'procedure' is automatically selected when withdrawal is indicated. For both **Human & Veterinary submissions**: When a marketing authorisation application (maa) submission is selected as submission type and the submission unit is a response then the user must indicate if the response contains request for change of applicant. If so, the relevant docs should be included as part of the submission (e.g. new electronic Application Form).	The submission description is automatically filled in for relevant post-authorisation procedures.
4	**For Human domain only:** For Type 2 variations, Extensions and MAA submissions a new radio button has been implemented to flag if the submission is 'Covid-19' related.	The selection is defaulted to option 'No'. If your submission is Covid-19 related, please ensure that you tick 'Yes'.



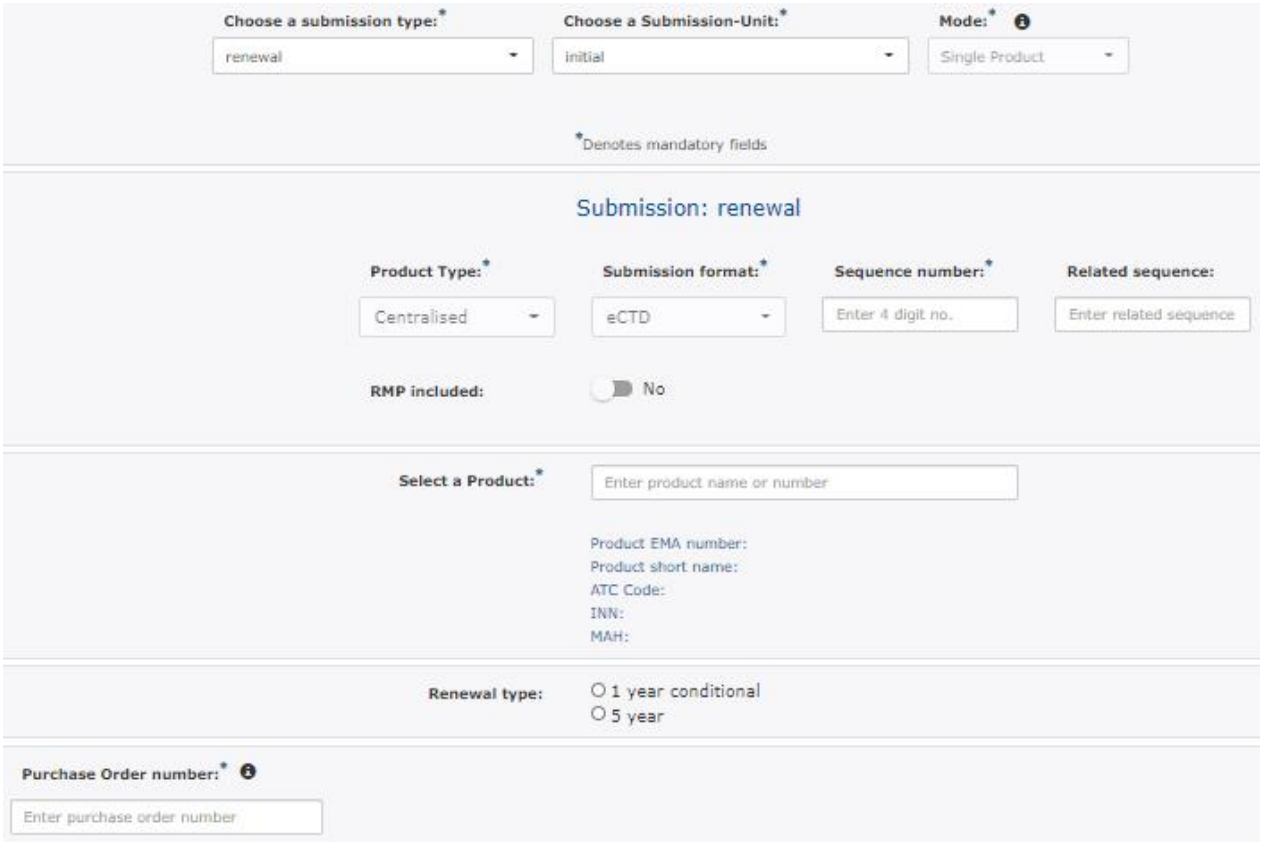
5	**For Human domain only:** For all variations with submission unit 'initial', a new mandatory radio button has been implemented to flag if the submission is 'Nitrosamine' related.	If your variation is submitted in order to comply with the Art 5(3) recommendation on nitrosamines, please ensure that you tick 'Yes'.

5	**Human domain:** For Centralised Procedure human submissions, the Product type and the submission format cannot be changed and must always be 'Centralised' and 'eCTD'. Submissions for Nationally Authorised Products that may be included for example in a referral procedure it is possible to change the product type and submission format to 'National' and 'NeeS' or 'Other' as applicable. Enter the submission eCTD or NeeS sequence number. For eCTD format submissions this number should always be the next sequential number in the product lifecycle. If a failure Acknowledgement is received, the same sequence number should be used unless the error relates to the sequence number itself. For initial MAA submissions the sequence number is normally 0000. To allow for easy cross referencing of related submissions; Users can optionally enter a related sequence number. **Veterinary domain:** In veterinary submissions, the Product type is by default set to "Centralised" and cannot be changed (apart the exception of worksharing and referral submissions). For Centralised Procedure veterinary submissions, the Submission format can be selected from the following options: "VNeeS (pharmaceutical product <version>)", "VNeeS (immunological product <version>)" or "Other". For MAA submissions, option "Other" cannot be used. For example, "VNeeS (pharmaceutical product v2.6)" means the structure follows the Guideline on eSubmission for Veterinary products - version 2.6, TABLE 1: Folder	The sequence number is always a numeric value (range from 0000 to 9999). More information on the related sequences can be found from the Harmonised technical eCTD guidance. If CTD is used as the format of part II (Quality) of a VMP dossier, the submission format to select is "VNeeS". As format requirements evolve over time in line with the EU Telematics eSubmissions Roadmap for use of VNeeS, applicants should always consult the Veterinary eSubmissions Website for current guidance on the mandatory or

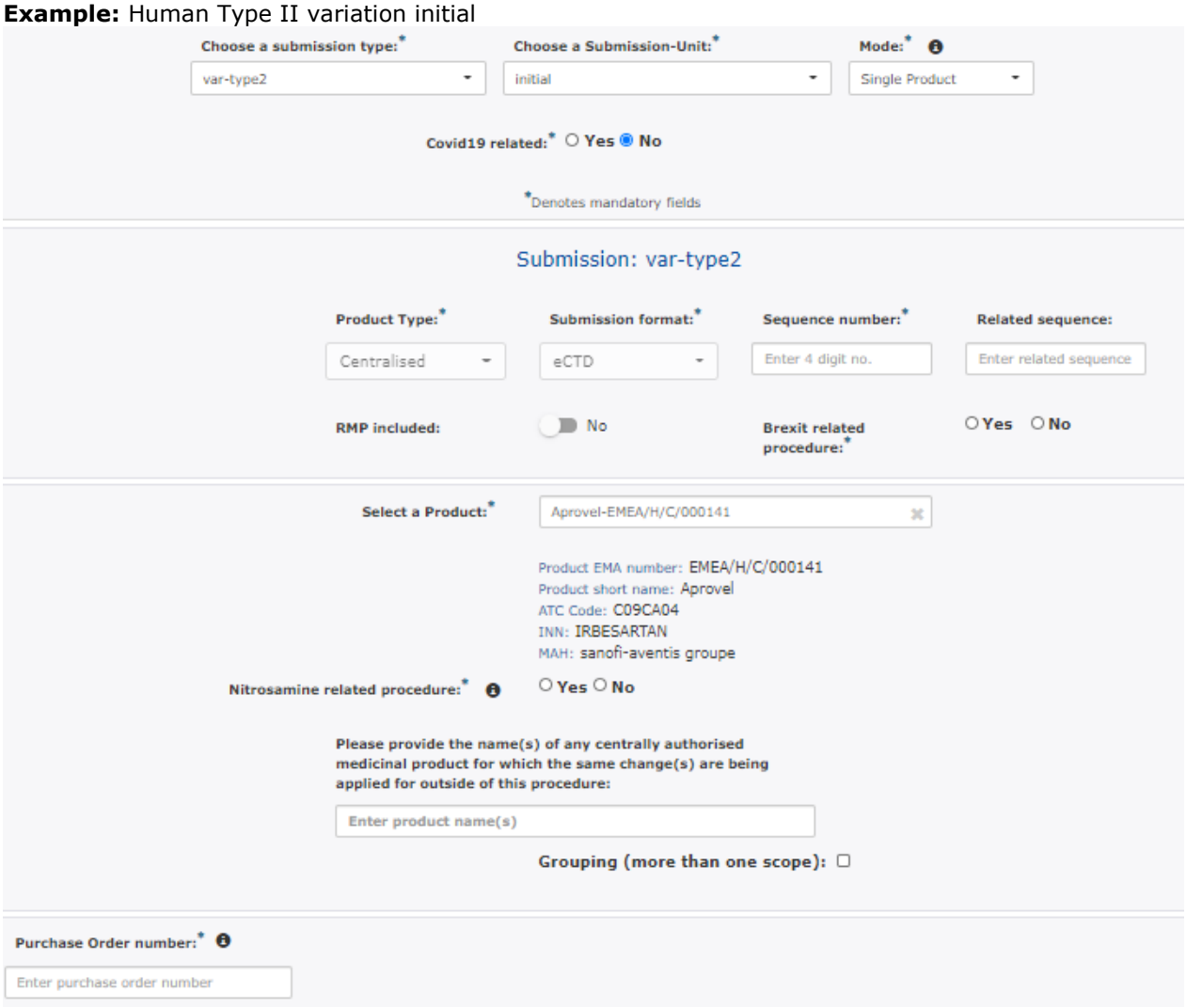
	structure and Standard files for an electronic application for a pharmaceutical product. "VNeeS (immunological product v2.6)" means the structure follows the Guideline on eSubmission for Veterinary products - version 2.6, TABLE 2: Folder structure and Standard files for an electronic application for an immunological product.	recommended format for their submission type. If the submission relates to an ASMF in CTD format, select "Other".
5	Depending on the submission type the information required is different. **Human domain:** For initial MAA submission; start typing in the 'Select product' field the product name or **any** part of the product number in format H0001234 For medical devices; start typing in the 'Select product' field the product name or any part of the product number in format H000123 for initial MAA submission and indicate using the tick box if the product is a medical device.  For any subsequent submissions of medical devices, you can search the product by name or typing H/D. For any other post-authorisation activity; start typing in the 'Select product' field the product name or **any** part of the product number in format H/C, H/D or H/W. Alternatively, you can simply enter the product number without the prefix letters. For human submissions, the Product type and the submission format cannot be changed and must always be 'Centralised' and 'eCTD'. Enter the submission eCTD sequence number. This number should always be the next sequential number in the product lifecycle. It is possible to enter the sequence number of any related sequence to cross reference related submissions. For 'initial' and 'reformat' submissions the related sequence number should be the same as the sequence number. For all other submission units, the related sequence should be different (smaller) than the sequence number. Users should indicate if a Risk Management Plan (RMP) is included and if yes, the RMP number must be provided for the following submission types: • MAA • Extension • Renewal • Variation Type IA • Variation Type IAIN • Variation Type IB • Variation Type II • PAM For all post authorisation CAP submissions when the submission unit is closing, and the closing sequence relates to multiple different procedures; users can add multiple procedure numbers from a predefined list to reference the	The EMA product number is available on the Eligibility confirmation letter as 'Product Reference'. The Eligibility Confirmation Letter indicates Product number e.g. H0002271 or V0001234. This Product Number (or Product Reference) remains the same throughout the product lifecycle and it should be used regardless what type of submission is being transmitted. Product numbers start H/C for human CAPs. If your product is authorised under article 58 (WHO) you can filter by typing H/W. If the product is medical device, you can filter by typing H/D. The submission format is automatically changed to 'other' when medical device is selected. The sequence number is always a numeric value (range from 0000 to 9999).

	submission by using 'Add related procedure' field. For variations Type IB and Type II it is possible to indicate the names of other CAPs for which the same changes are being applied in a separate submission. The names of these products are entered using a free text field. For initial renewal submissions the MAH should select the renewal type by indicating the length of the requested renewal – conditional 1-year renewal or 5-year renewal. For human 'pam' (except pam-capa) and pass 107n, pass 107q and pass 107q submissions an additional attribute 'Pam Code' must be selected. The Pam code is a mandatory field with a dropdown list of relevant codes. **Human and Veterinary domains:** It is now mandatory to indicate if the submission contains a Brexit related procedure. This is applicable for initial submissions for the following submission types: • Variations Type IA (H&V) • Variations Type IA_{IN} (H&V) • Variations Type IB (H&V) • Variations Type II (H&V) • Transfer MA (H&V) • Notification 61-3 (H only) **Veterinary domain:** For initial MAA submission; start typing in the 'Select product' field **any** part of the product number in format 001234 (see Example: Veterinary Initial MAA below). For any post-authorisation activity; start typing in the 'Select product' field the product name or **any** part of the product number (see Example: Veterinary Extension below).	Product names are not shown for veterinary submissions prior to the initial application for data protection. Product numbers for veterinary CAPs in post-submission start with EMEA/V/C and are one digit shorter but the number is retained for the product in question. The EMA product number is available on the Eligibility confirmation letter as 'Product Reference'. The Eligibility Confirmation Letter indicates Product number e.g. H0002271 or V0001234.

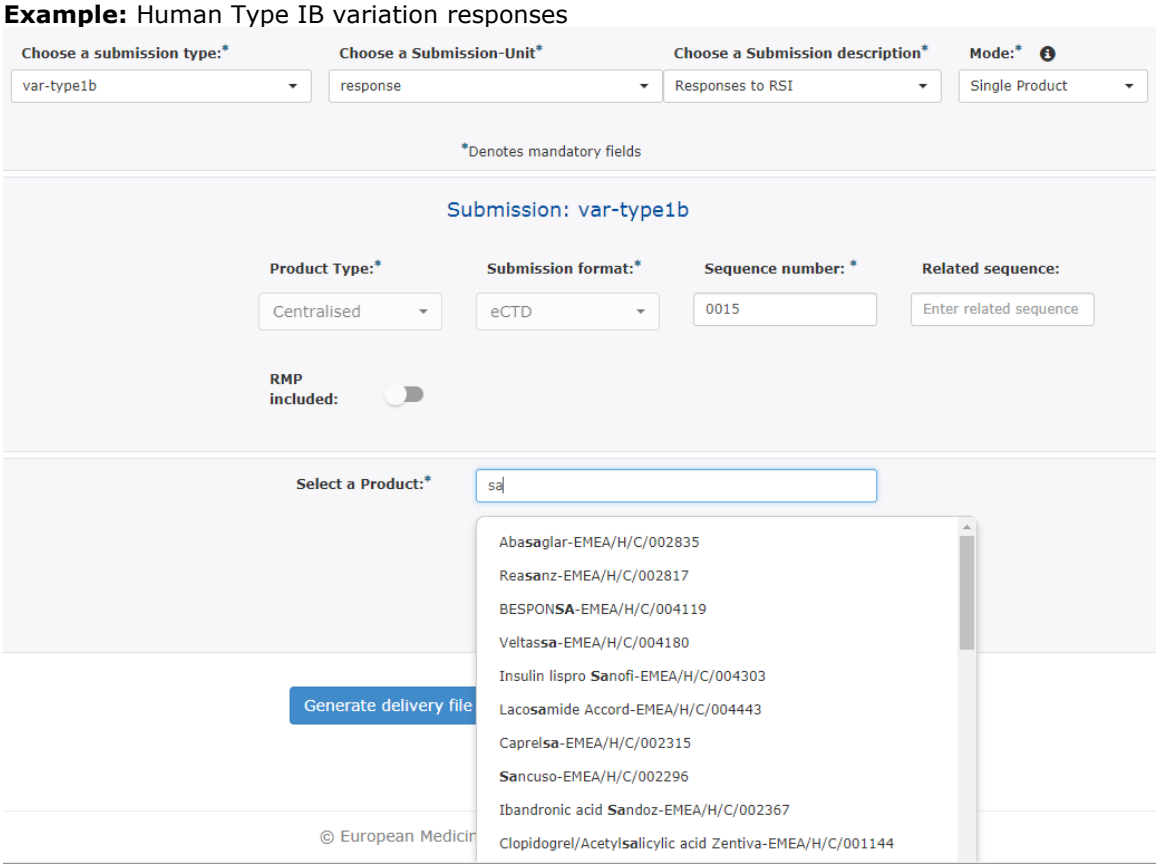
Example: Human Renewal initial

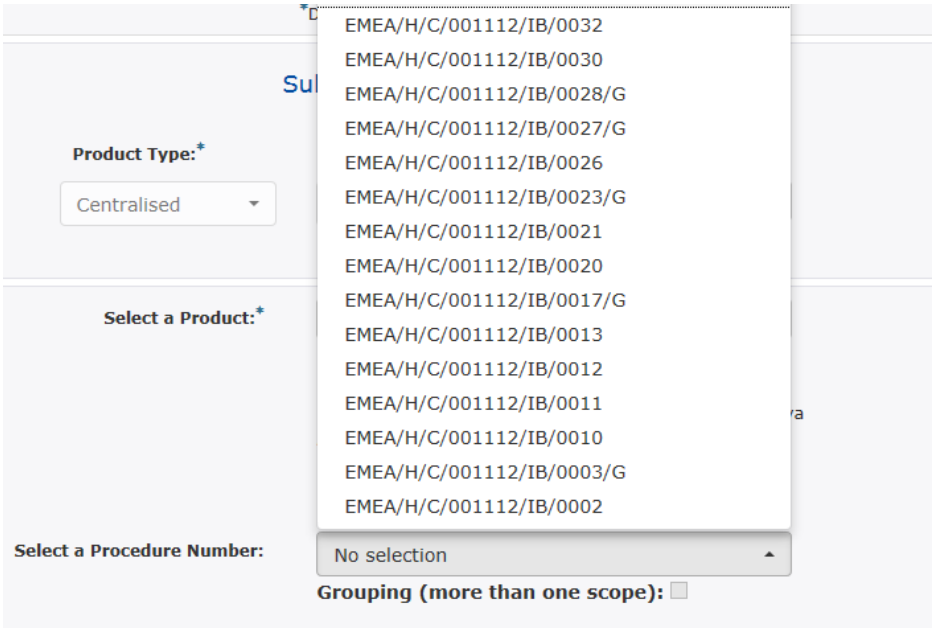


Example: Human Type II variation initial



Example: Human Type IB variation responses

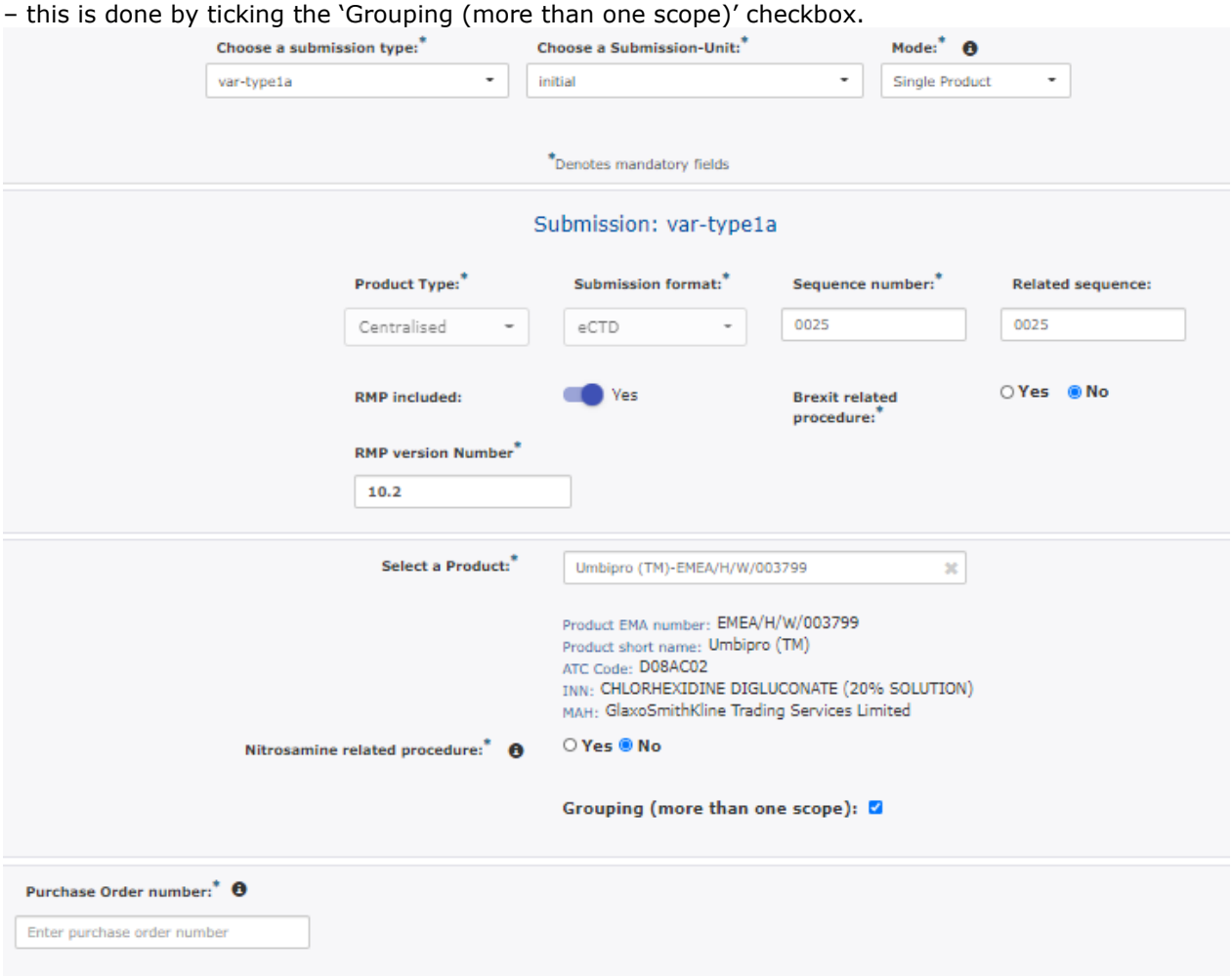




Example: Human Type IA variation – **grouping of multiple scopes** affecting a **single product***

In the case that the grouping variation concerns a single product, the eCTD envelope 'Mode' is 'Grouping' and the XML delivery file 'Mode' is 'Single Product'.

In case of submission unit 'initial' is used it is now possible to indicate that multiple scopes are included – this is done by ticking the 'Grouping (more than one scope)' checkbox.

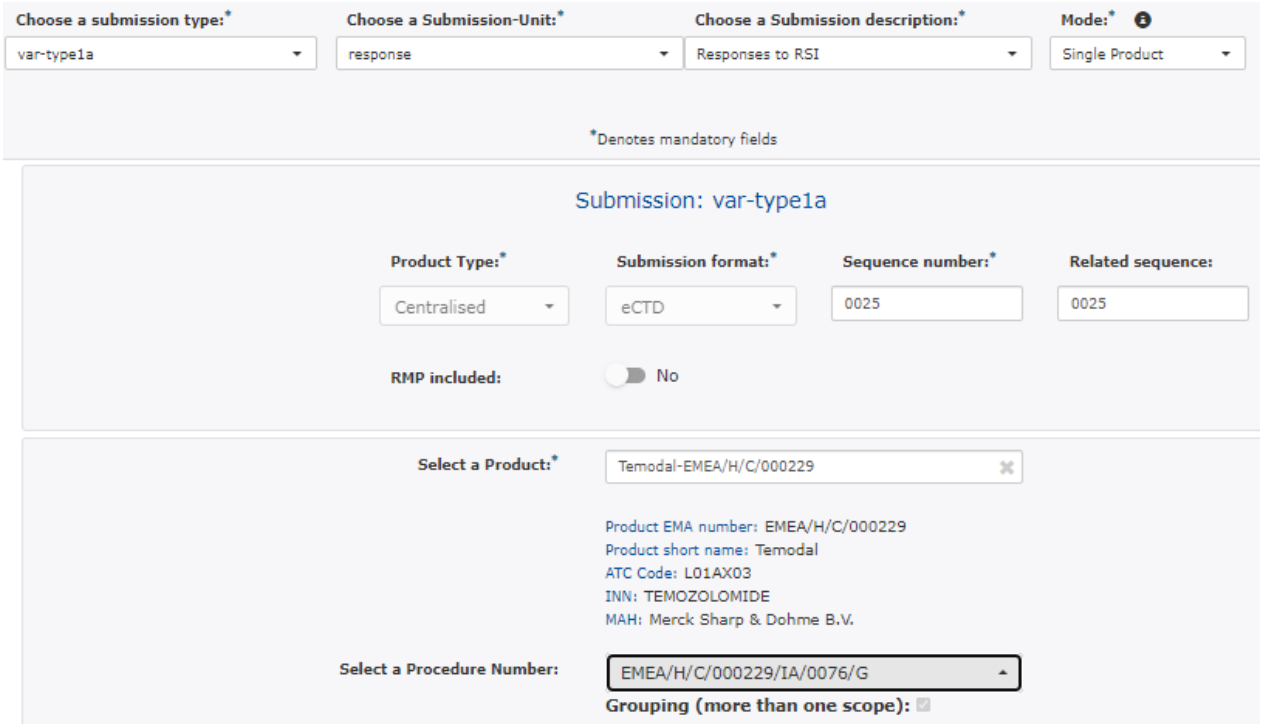


In case the submission unit is '**responses'** submission description 'Responses to RSI' is automatically selected. The Mode should remain 'single product'.

A procedure number should be selected from list of procedure numbers for post-authorisation procedures. The procedure number can only be selected for subsequent submissions after the initial sequence. The procedure number is selected – if available - from the list of available procedure numbers, the numbers listed depend on the submission type. This number is provided to you at the time of the start of the procedure. In case the correct procedure number **is not found** from the list, please **contact the EMA service desk** or **leave the field empty** .

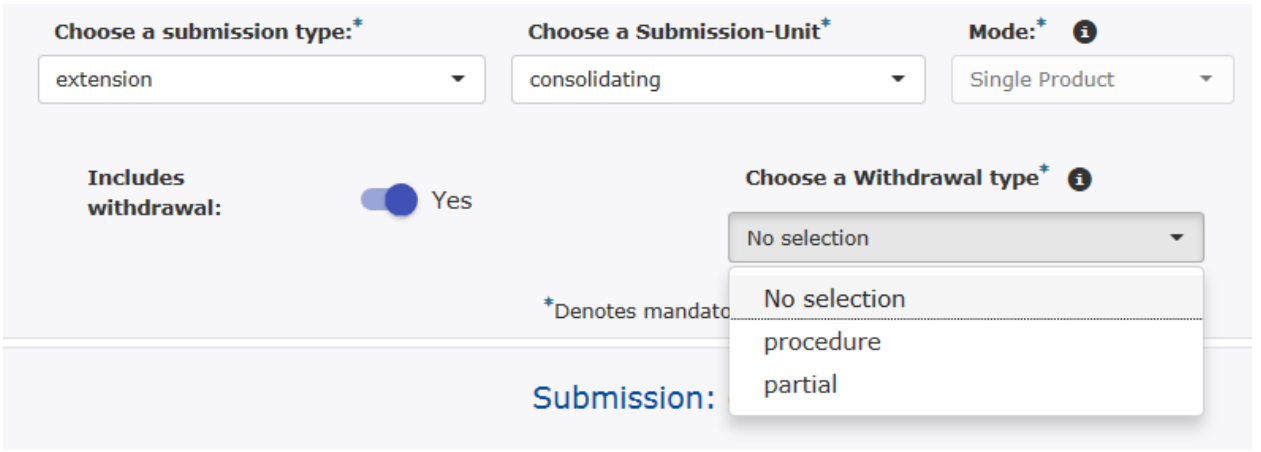
When multiple scopes are included in a single variation, it is indicated with G at the end of the procedure number.

If you are not able to find the correct procedure number from the list. Please contact the EMA service desk.

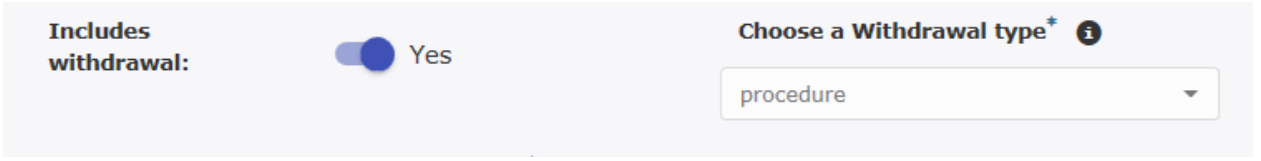


Example – Extension **- consolidating – including withdrawal**

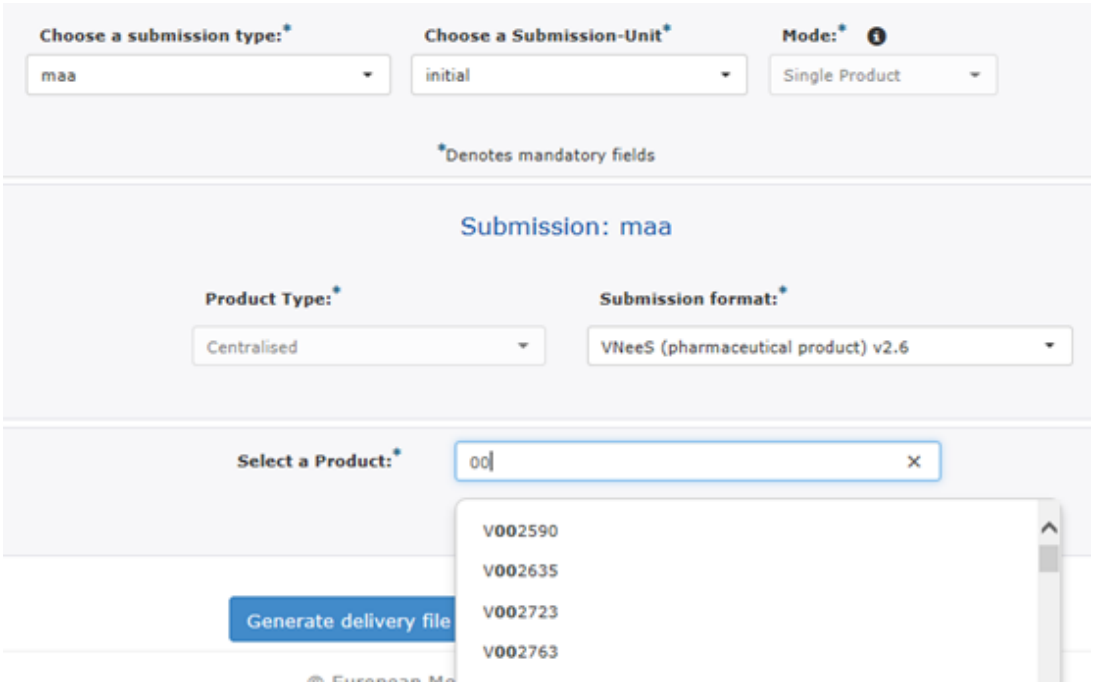
In the case that the submission type is extension or variation and the submission unit is consolidating and it is indicated that the submission includes withdrawal (by selecting 'yes', the user should select if the withdrawal concerns the whole procedure or is partial i.e. is relevant to only specific scopes.



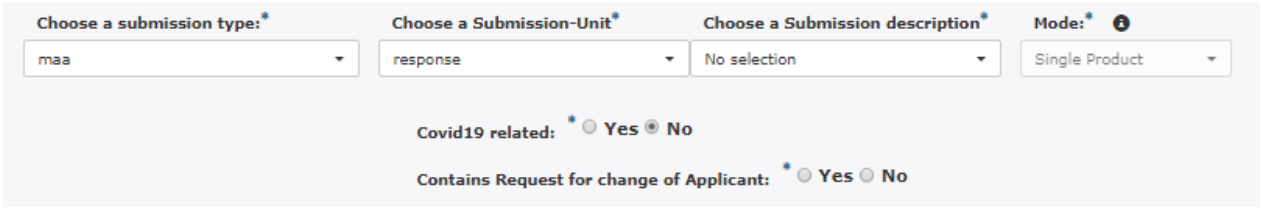
For all other submission types when 'consolidating' is selected, the withdrawal type is defaulted to 'procedure'.



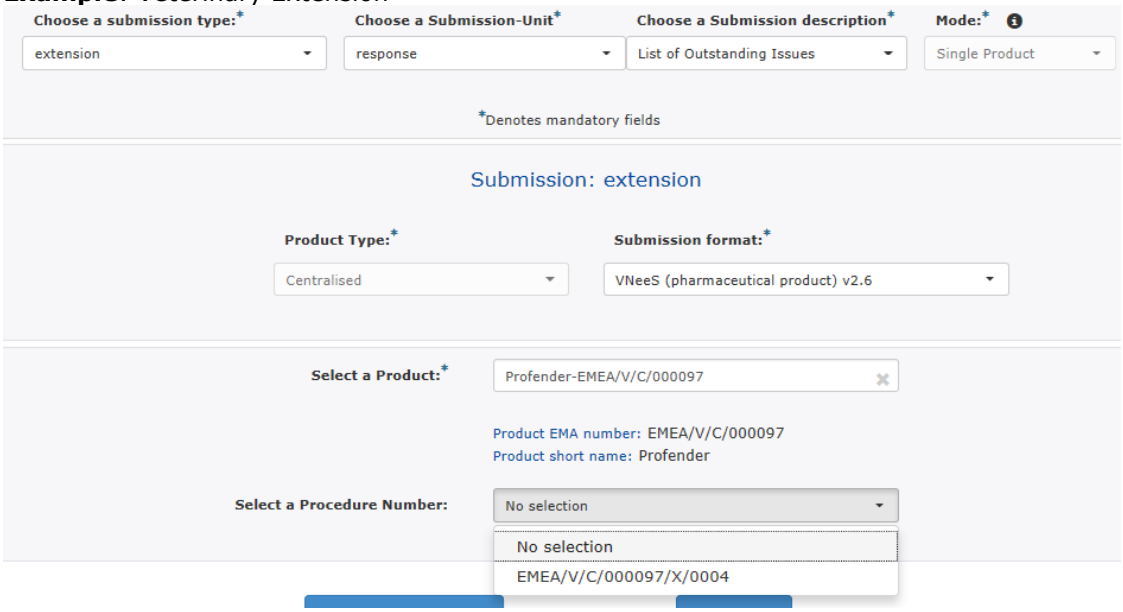
Example: Veterinary Initial MAA



Example: Human and Veterinary maa – response – contains a request for change of Applicant



Example: Veterinary Extension



In case the submission unit is 'responses' submission description List of Questions or List of Outstanding Issues should be selected.

A procedure number should be selected from list of procedure numbers for post-authorisation procedures. The procedure number can only be selected for subsequent submissions after the initial

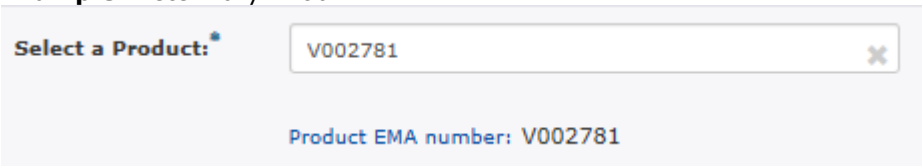
sequence. The procedure number is selected – if available - from the list of available procedure numbers, the numbers listed depend on the submission type. This number is provided to you at the latest at validation / start of the procedure. In case the correct procedure number **is not found** from the list, please contact **vet.applications@ema.europa.eu** or **leave the field empty**.

The Procedure number is only requested for annual re-assesment, extensions, variations, renewals, transfers and lifting of suspensions. It does not apply in initial submissions and in WS/IG submissions. In case of WS/IG submission, the WS/IG number should be selected from the list provided.

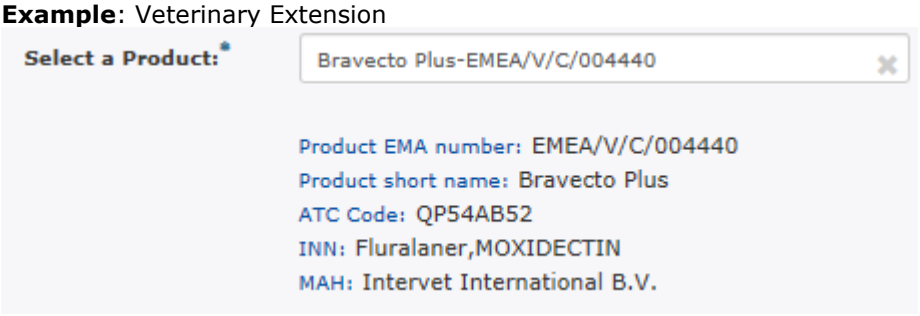
6	Select the product and check that the correct product is reflected	

Example: Human domain

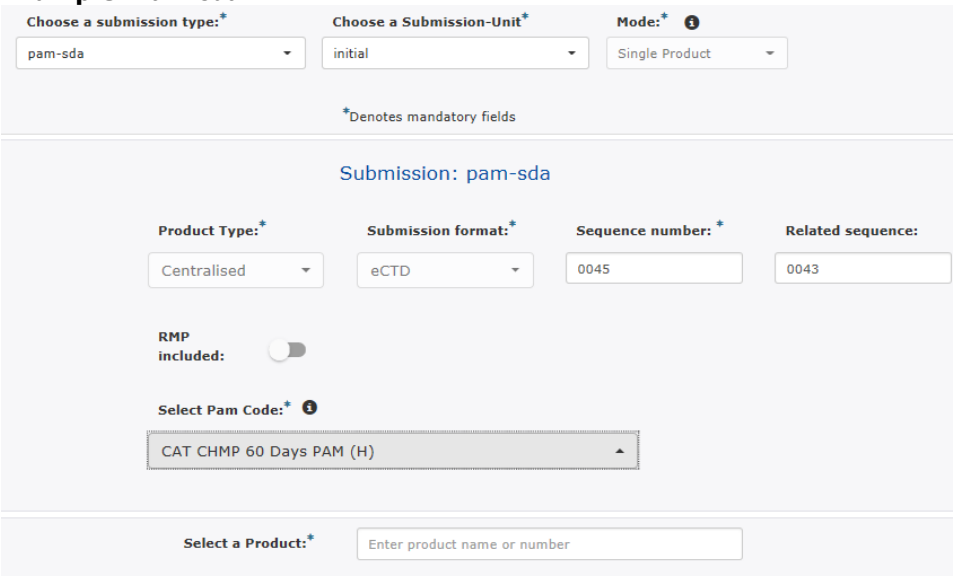
Example: Veterinary Initial MAA



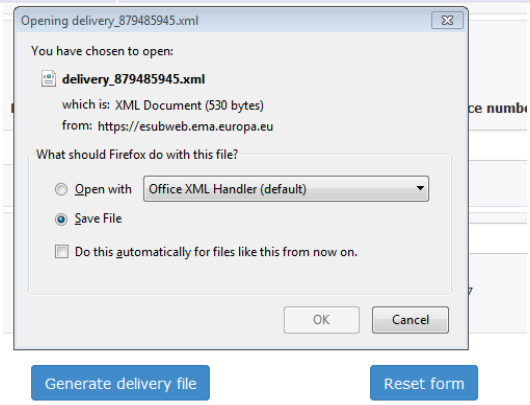
Example: Veterinary Extension



Example: Pam-sda



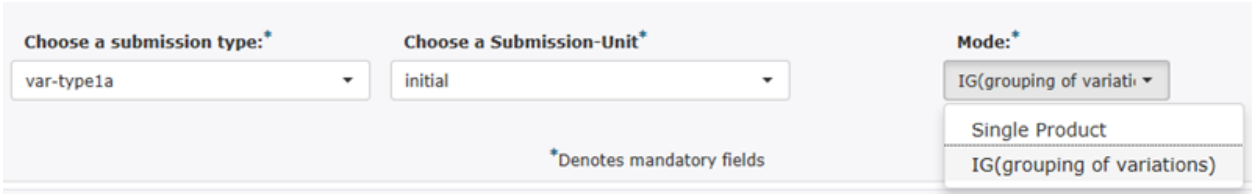
7	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

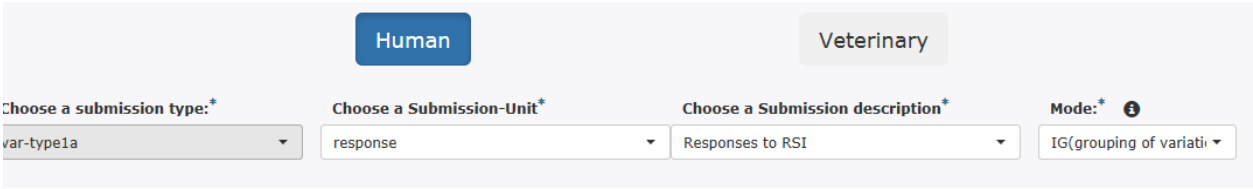


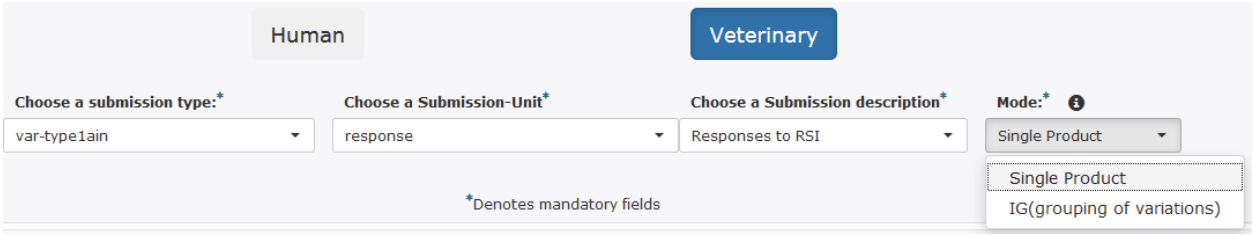
8	If you notice you have made an error or you wish to generate another or different delivery file, click 'Reset form' button.	It is recommended to 'Reset' the form before creating a new delivery file using different submission type.

4.2. Create delivery file for IG variation submission

Step	Description	Notes
1	Select 'var-type1a' or 'var-type1ain' from the regulatory activities list (submission type). Select the relevant 'submission unit' from the list. Select the correct mode: IG (Grouping of variations) The Agency will allocate a 'high-level' cross-products IG procedure number, which will be used for the handling of procedures which affect more than one medicinal product. A procedure code (abbreviation) is used for such groups of Type IA/ IA_{IN} variations i.e. "IG". As the 'high-level' number cannot be allocated to one single product, the procedure number will therefore contain "xxxx" as a placeholder for the product number. Example: EMEA/H/C/xxxx/IG/002. **Note:** For grouping of several different changes affecting the **same** product – select 'Single Product' in the XML delivery file and 'Grouping' in the eCTD envelope. This leads to a difference in the eCTD envelope and in the XML delivery file which is acceptable as the 'Mode' is used for different purpose in the eCTD envelope and in the XML delivery file. **Please note** that requesting this **high-level number** in advance is **mandatory** since this number must be included in the xml delivery file.	This 'high-level' procedure number can be obtained from the Agency shortly before submission by sending your request with a copy of the draft cover letter to the EMA service desk or vet.applications@ema.europa.eu. **Note** that **IG variations** are those that **affect more than one MA**. If your variation is **a grouping of several type IA changes** but affects **a single product**, do **not** select the IG option. Leave the 'Mode' as **Single** (as this is referring to a single product). Please note that in the eCTD envelope mode value 'Grouping' should be selected for 'Grouped variations'. More information on 'Grouping of variations' can be found from the Regulatory Post-Authorisation Guide (choose either 'human' or 'veterinary' tabs).

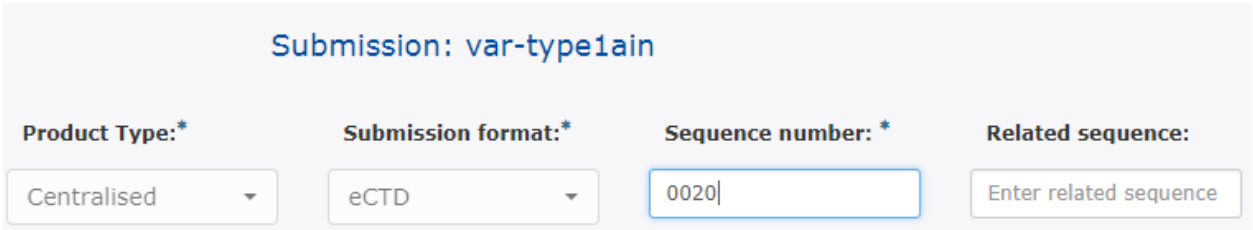




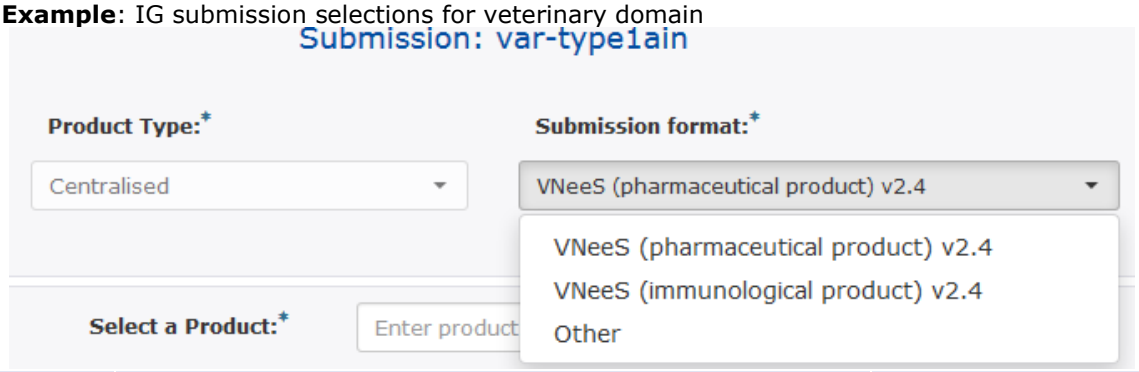


2	**Human domain:** The Product type and the submission format cannot be changed and must always be 'Centralised' and 'eCTD'. Enter the submission eCTD sequence number. This number should always be the next sequential number in the product lifecycle. For initial MAA submissions this is normally 0000. It is possible to enter related sequence number to cross reference related submissions. For initial submission the related sequence number should be equal to the sequence number **Veterinary domain:** The Product type cannot be changed and must always be 'Centralised'. The Submission format can be selected from three of the following options: "VNeeS (pharmaceutical product) v2.6", "VNeeS (immunological product) v2.6" or "Other".	The sequence number is always a numeric value (range from 0000 to 9999). If CTD is used the format of part II of a VMP dossier, the submission format to select is "VNeeS".

Example: IG submission selections for human domain

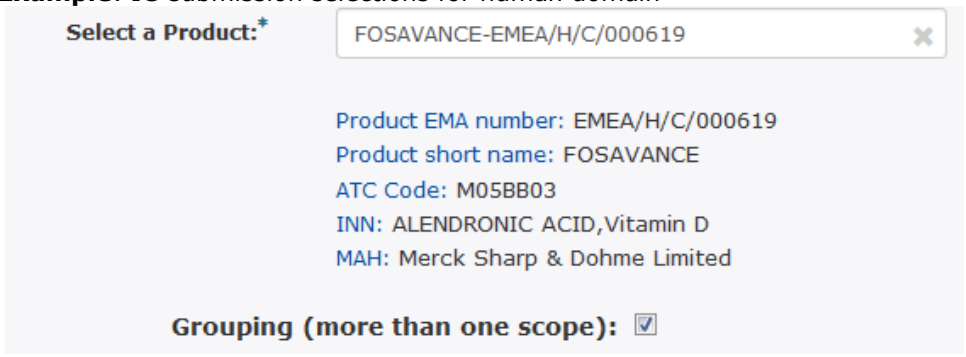


Example: IG submission selections for veterinary domain

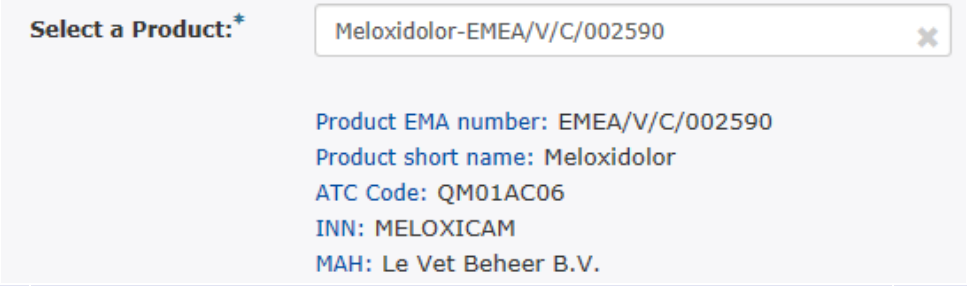


3	Search for the relevant product by typing any part of the product name or product number in the 'Select product' field. The more you type the more the list filtered. The product ATC code, INN and the MAH name are also shown for visual confirmation (these are not shown for Vet maa applications due to confidentiality).	From 1 January 2018, for veterinary IG submissions, a separate XML delivery file must be created, and a separate submission made for each of the Centrally Authorised Products included in the procedure. An identical package covering all relevant products should be submitted for each, with only the XML delivery file changing for each product.

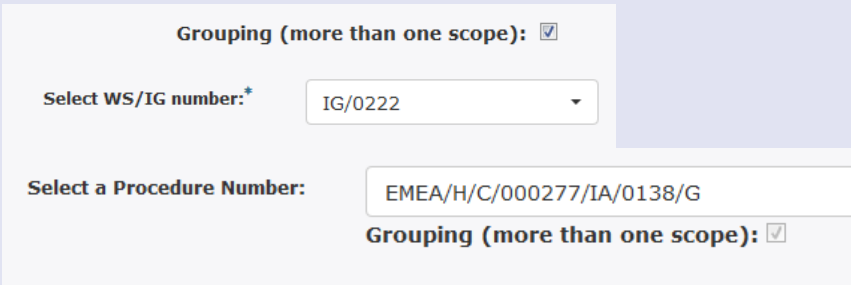
Example: IG submission selections for human domain



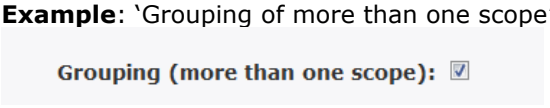
Example: IG submission selections for veterinary domain



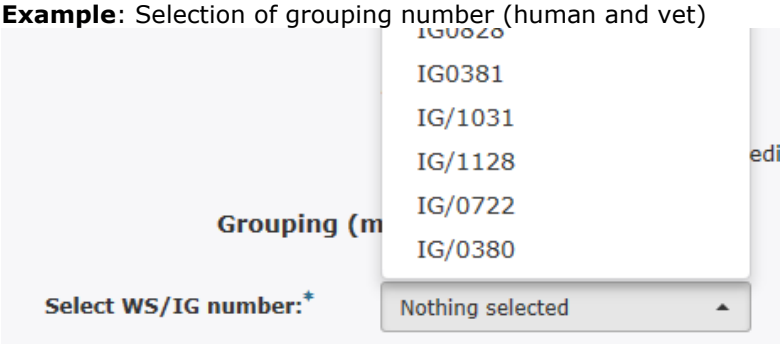
4	Select the Grouping (IG) number from the list. Please note that **IG variations** are those that **affect more than one product**. The system displays those 'Grouping numbers' that contain the selected product i.e. it is not possible to select a grouping number if the procedure doesn't contain that particular product. For procedure that has multiple changes for a single product, select mode 'Single Product' in the XML delivery file and Grouping in eCTD envelope. Indicate that the submission covers multiple scopes by ticking the box 'Grouping (more than one scope)'. When multiple scopes are included in a single variation (response	If the grouping (IG) number is not available contact the EMA service desk for human submissions, or vet.applications@ema.europa.eu for veterinary.

	submissions), it is indicated with G at the end of the procedure number. When selecting a procedure number for variation that contains multiple scopes an automatic tick box is filled by the system to indicate 'Grouping (more than one scope). It is not necessary/possible to select the procedure number when WS or IG number is selected. 	

Example: 'Grouping of more than one scope'



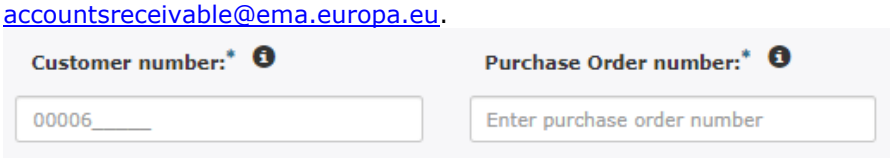
Example: Selection of grouping number (human and vet)



6	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

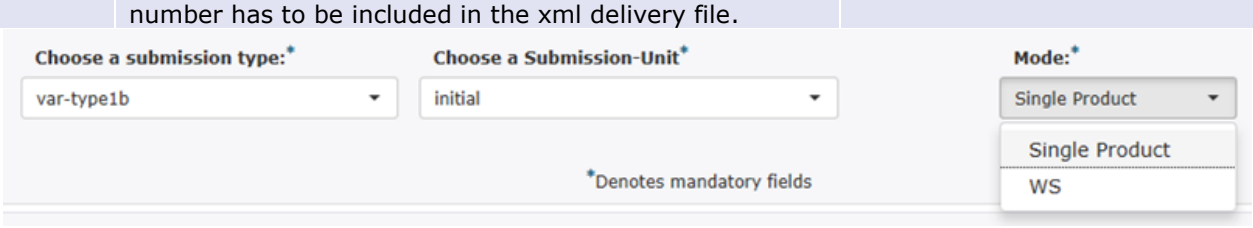
It is not necessary/possible to select the procedure number when WS or IG number is selected.

Human and Veterinary submissions: In case of initial submission of a Worksharing variation (WS) or MAA application, the EMA SAP customer number and purchase order number should be provided. For initial MAA submissions the customer number needs to be provided by the applicant.
More information on the customer number can be found from the '[How to pay]' in the pre-submission guidance. For queries on the purchase order number, please contact accountsreceivable@ema.europa.eu.

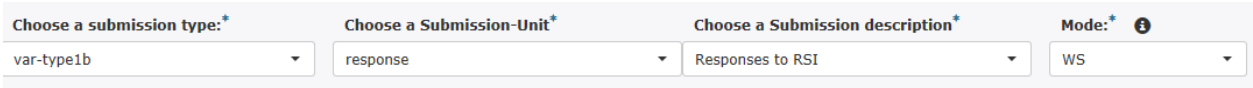


4.3. Create delivery file for WS variation submission for Centrally Authorised Products (CAPs)

Step	Description	Notes
1	Select 'var-type1b' or 'var-type2 from the regulatory activities list. Select the relevant 'submission unit' from the list. The 'submission description' Responses to RSI is automatically selected. Select the correct mode: WS (worksharing of variations) In order to facilitate the planning of a worksharing procedure, MAHs are advised to inform the Agency at least two months in advance of the submission of a variation or group of variations to be subject to a worksharing procedure, together with an explanation as to why the holder believes that a worksharing procedure is suitable, by means of a 'letter of intent'. **Please note that requesting the worksharing arrangement in advance is mandatory. The WS** number has to be included in the xml delivery file.	More information on 'Worksharing' can be found from the Regulatory Post-Authorisation Guide (search in 'human' or 'veterinary' guidance as appropriate). A letter of intent template must be filled and sent to the EMA service desk to obtain the WS number. For vet worksharings, it is sent to vet.applications@ema.europa.eu.

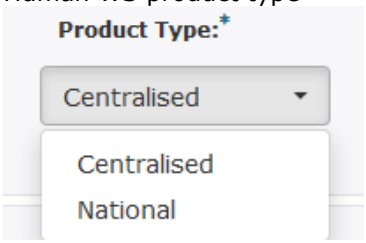


or

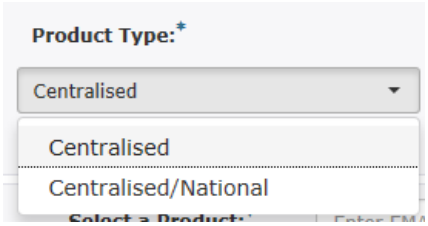


2	As the Worksharing procedure may contain both Centrally and Nationally Authorised products, it is important to ensure that the correct 'Product type' is selected from the dropdown menu. For human submission, select between 'Centralised' and 'National'. For veterinary submission, select between 'Centralised' or 'Centralised/National'.	**VET specific note:** The difference for the vet domain stems from the fact that each WS-related submission can contain documentation for all affected products in a single package. Select 'Centralised/National' if your WS includes both CAPs and NAPs (including MRP or DCP products).

Human WS product type



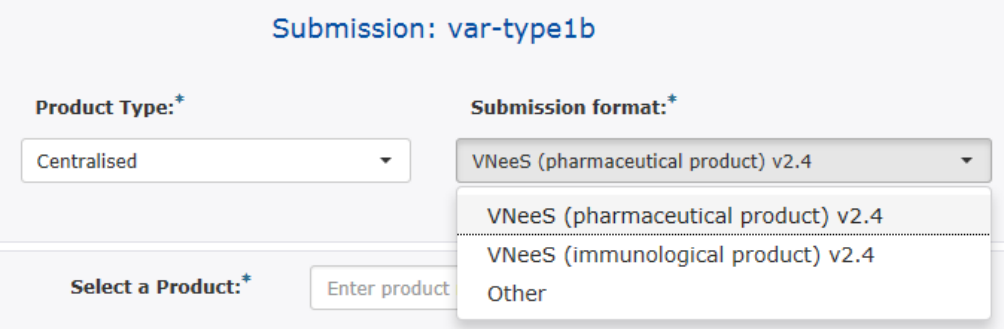
Veterinary WS product type



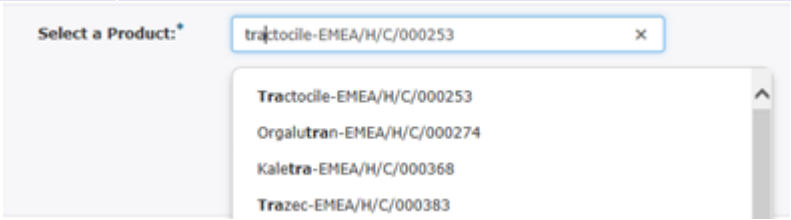
3	**Human domain:** When 'Centralised' product type is selected, the submission format cannot be changed and must always be 'eCTD'. Enter the submission eCTD sequence number. This number should always be the next sequential number in the product lifecycle. Optionally enter any related sequence number to cross reference related submissions. **Veterinary domain:** When 'Centralised' product type is selected, the Submission format can be selected from three of the following options: "VNeeS (pharmaceutical product) v2.6", "VNeeS (immunological product) v2.6" or "Other"..	The sequence number is always a numeric value (range from 0000 to 9999). If CTD is used the format of part II of a VMP dossier, the submission format to select is "VNeeS".

Example: Type IB worksharing (initial) for human domain

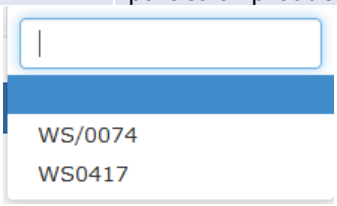
Example: Type IB worksharing for a VMP – selection options



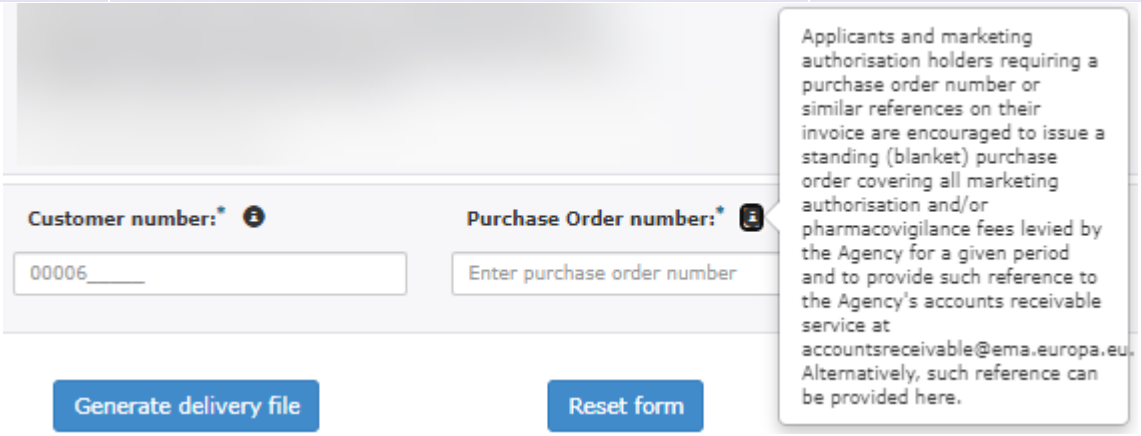
4	Search for the relevant product by typing any part of the product name or EMEA product number in the 'Select product' field. The more you type the more the list is filtered. The product ATC code and INN are now also shown for visual confirmation.	From 1 January 2018, for veterinary WS submissions, a separate XML delivery file must be created and a separate submission made for each of the Centrally Authorised Product included in the procedure. The package included in the submission should be the same for all products



5	If Product type 'Centralised' is selected the product selection is linked to relevant WS numbers. The system then displays those 'worksharing numbers' that contain the selected product i.e. it is not possible to select a WS number if the procedure doesn't contain that particular product.	If you cannot find the WS number from the list, please contact the EMA service desk for Human variationsor vet.applications@ema.europa.eu for veterinary variations.

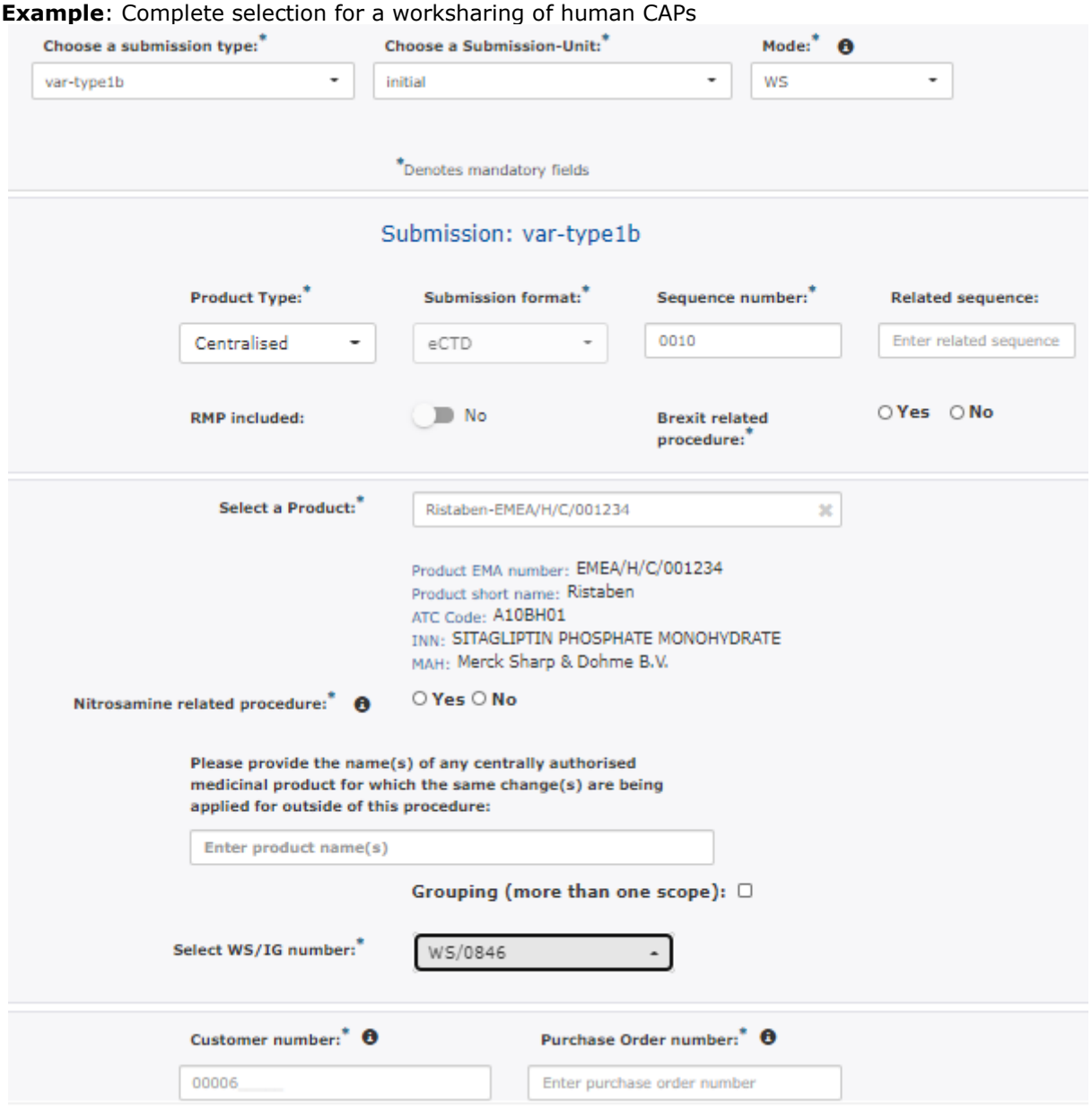


6	In case of initial submission of a Worksharing variation (WS) or MAA application, the EMA SAP customer number and purchase order number should be provided. More information on the customer number can be found from the 'How to pay' in the pre-submission guidance. The Purchase Order Number is now a mandatory field.	More information on the customer number can be found from the 'How to pay' in the pre-submission guidance. For queries on the purchase order number, please contact accountsreceivable@ema.europa.eu

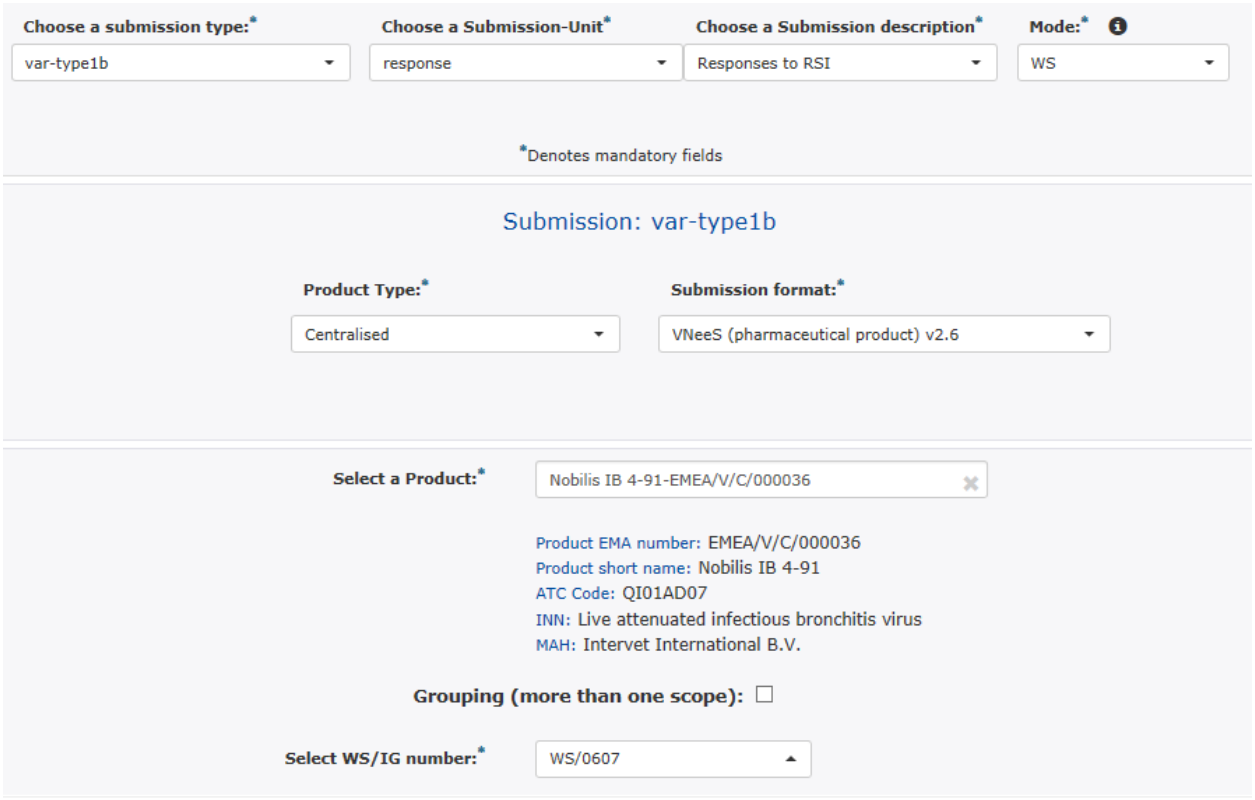


7	Confirm the details are correct and click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

Example: Complete selection for a worksharing of human CAPs

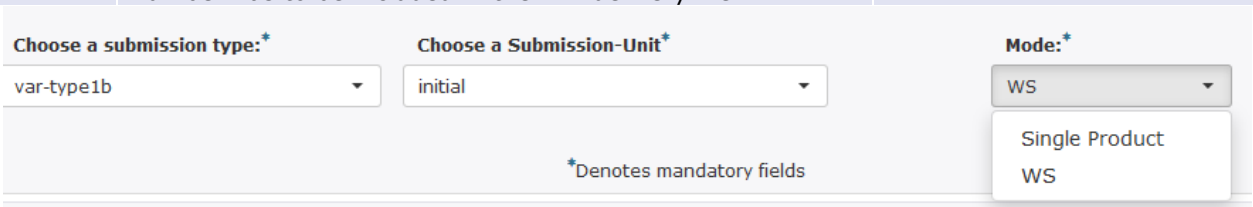


Example: Complete selection for a worksharing of veterinary CAPs

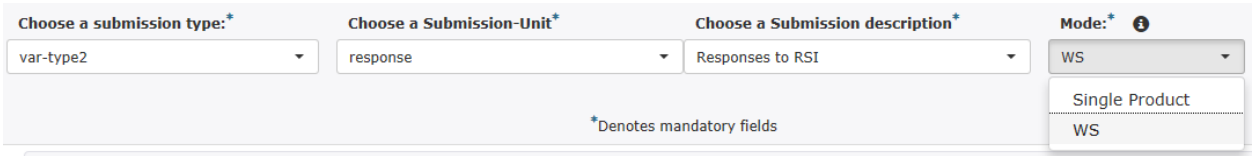


4.4. Create delivery file for WS variation submission for Nationally Authorised Products (human only)

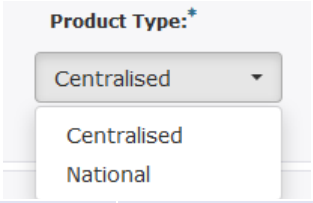
Step	Description	Notes
1	Select 'var-type1b' or 'var-type2 from the regulatory activities list (submission type). Select the 'submission-unit' from the list. Select the mode: WS (worksharing of variations) In order to facilitate the planning of a worksharing procedure, MAHs are advised to inform the Agency at least two months in advance of the submission of a variation or group of variations to be subject to a worksharing procedure, together with an explanation as to why the holder believes that a worksharing procedure is suitable, by means of a 'letter of intent'. **Please note that requesting the worksharing arrangement in advance is mandatory. The WS** number has to be included in the xml delivery file.	More information on 'Worksharing' can be found from the Regulatory Post-Authorisation Guide. A letter of intent template must be filled and sent to the EMA service desk to obtain the WS number.



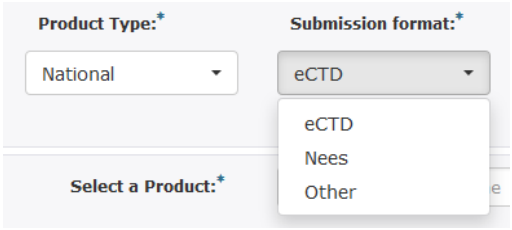
or



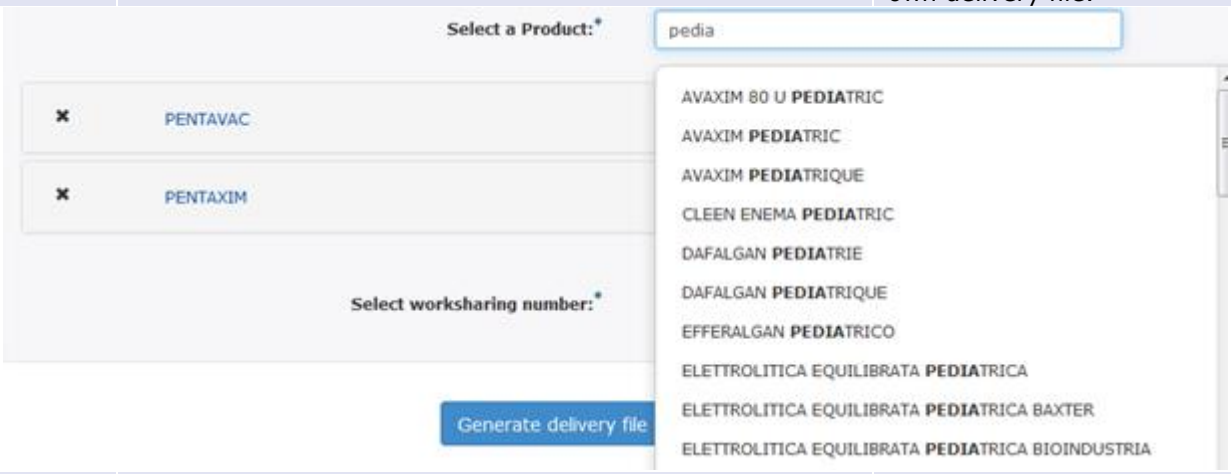
2	As the Worksharing procedure may contain both Centrally and Nationally Authorised products, it is important to ensure that the correct 'Product type' is selected from the dropdown menu.	



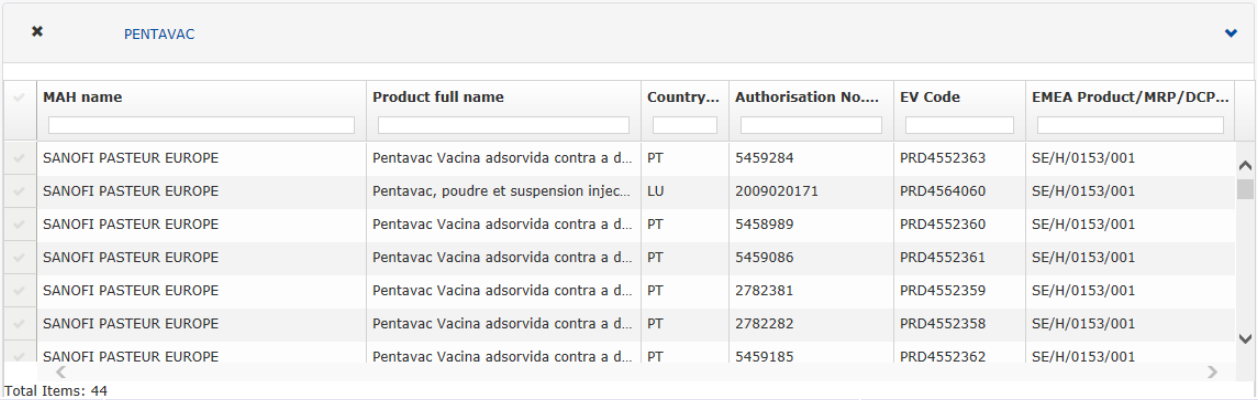
3	If 'Product type' National is selected the submission format should be selected. Ensure that you submit in the format that the product lifecycle is in the National Competent Authority which should now be eCTD following the requirement for mandatory eCTD for all products since 1st January 2019.	



4	Enter the submission eCTD sequence number. This number should always be the next sequential number in the product lifecycle. Enter any related sequence number to cross reference related submissions.	The sequence number is always a numeric value (range from 0000 to 9999)
5	Search for the relevant product(s) by typing any part of the product name in the 'Select a product' field. The more you type the more the list filtered. The list of Nationally Authorised Products with retrieved from XEVDMP (Art. 57 database).	It is possible to select more than one product name from the list to ensure that all products and presentations are selected. It should be noted that the submissions cannot be 'grouped' each eCTD sequence will need to be submitted separately with its own delivery file.

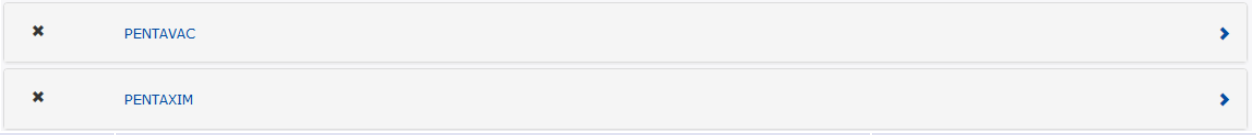


6	Expand the product details by clicking anywhere in the field with the selected product name and proceed to filter and select the relevant products/presentations. Multiple criteria may be used to filter the product selection.	The product EV code is also now displayed to help selection of the correct product/presentation.

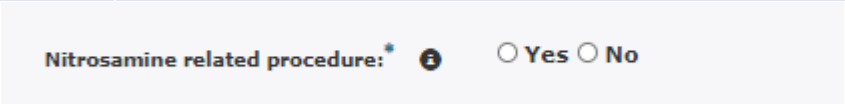


7	You can select all products/presentations by clicking to the field next to 'MAH name' field. Alternatively, click individual lines to select relevant products/presentations.	At least one of the products/presentation must be selected.

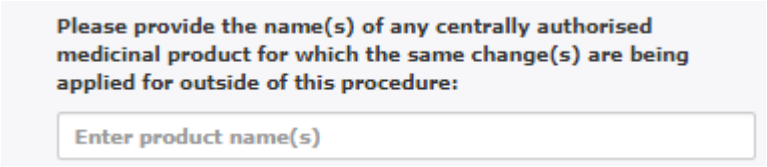
8	Close the selection by clicking anywhere in the field with the product name and repeat the previous step to include all products/presentations for which a single submission sequence has been prepared for.	



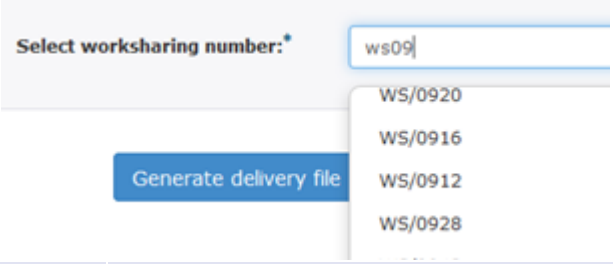
9	Indicate if the procedure is related to the Art. 5(3) recommendation Nitrosamines.	



10	You can provide the name(s) of any CAPs for which the same change(s) are being applied outside of this procedure using the free text field	



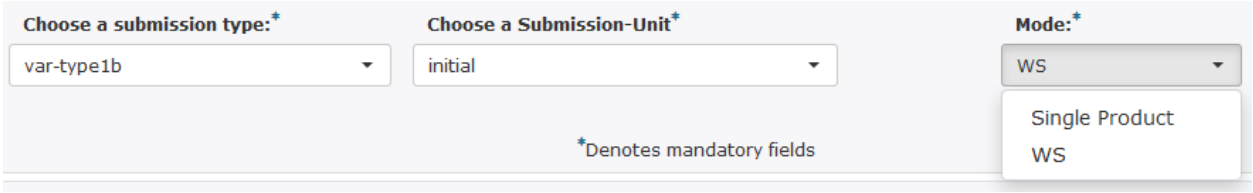
11	If 'Product type' National is selected the WS number is not limited to the products selected. Enter/search for the WS number.	If your WS number is not available contact the EMA service desk



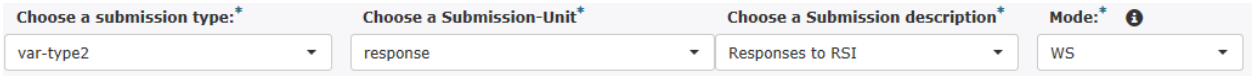
10	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

4.5. Create delivery file for WS variation submission including both CAPs and NAPs (veterinary only)

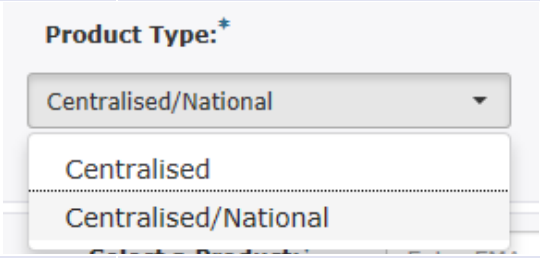
Step	Description	Notes
1	Select 'var-type1b' or 'var-type2 from the regulatory activities list ('submission type'). Select the 'submission-unit' from the list. Select the correct mode: WS (worksharing of variations) **Please note that requesting the worksharing arrangement in advance is mandatory. The WS** number has to be included in the xml delivery file.	More information on 'Worksharing' can be found from the Veterinary Regulatory Post-Authorisation Guide. A letter of intent template must be filled and sent to vet.applications@ema.europa.eu to obtain the WS number.



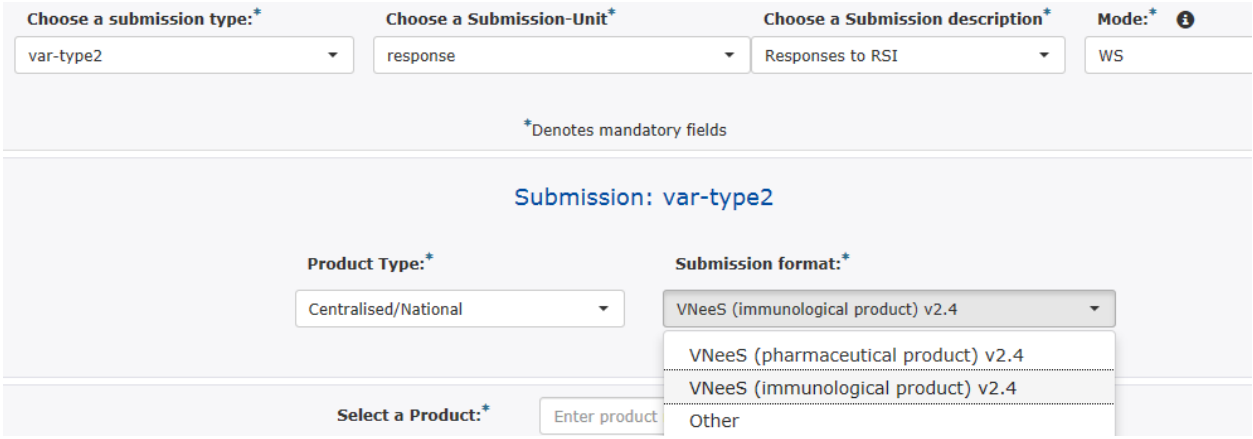
or



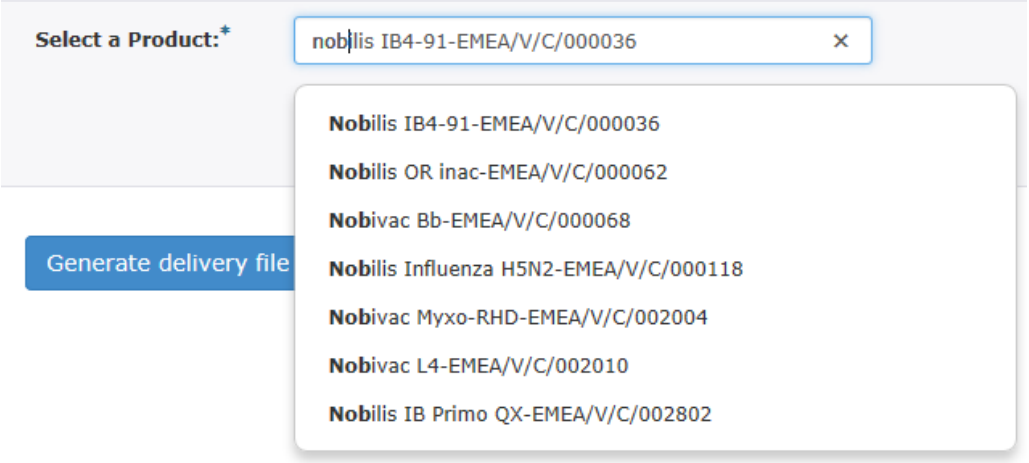
2	As the worksharing procedure may contain both Centrally and Nationally Authorised products, it is important to ensure that the correct 'Product type' is selected from the dropdown menu. In this case, select the 'Centralised/National' option.	The difference for the vet domain stems from the fact that each WS related submission can contain documentation for all affected products in a single package.



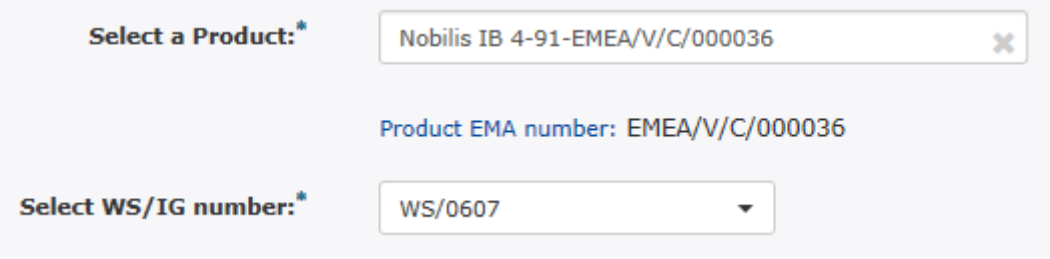
3	When Product type 'Centralised/National' is selected the Submission format can be selected from three of the following options: "VNeeS (pharmaceutical product) v2.4", "VNeeS (immunological product) v2.4" or "Other".	If CTD is used as the format of part II of a VMP dossier, the submission format to select is "VNeeS".



4	Search for the relevant lead product by typing any part of the product name in the 'Select a product' field. The more you type the more the list filtered.	From 1 January 2018, for veterinary IG submissions, a separate XML delivery file must be created and a separate submission made for each of the Centrally Authorised Products included in the procedure. An identical package covering all relevant products should be submitted for each, with only the XML delivery file changing for each product.



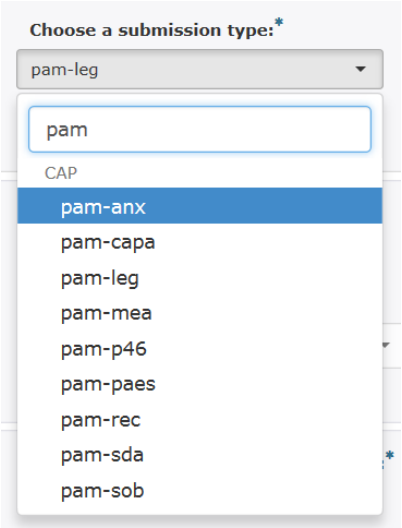
5	Enter/search for the WS number linked to the lead CAP product and select the WS number. Note: There is a known issue affecting the availability of product details (product name, MAH name, ATC code, INN and the MAH when Centralised/National is selected)	If your WS number is not available contact vet.applications@ema.europa.eu



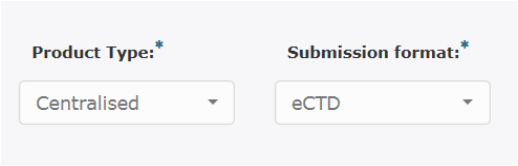
6	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

4.6. Create delivery file for PAM (Post-Authorisation Measure) submission for Centrally Authorised Products (human only)

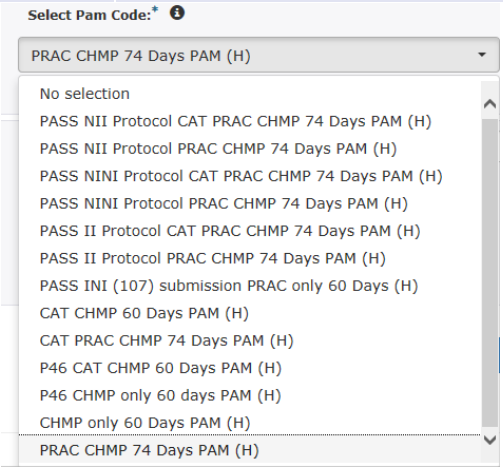
Step	Description	Notes
1	Select pam type (ANX, LEG, MEA, P46, REC, SDA, SOB) from the regulatory activities list (submission type) in line with the instructions provided in the PAM Submission form Select the 'submission-unit' from the list. This should in most cases be 'initial' or 'response'.	Submission unit 'Consolidatin' is now available for PAM submissions.



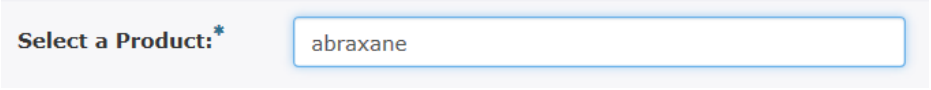
2	As PAM submissions refer to Centrally Authorised products, the Product type 'Centralised' is selected automatically from the dropdown menu.	
3	The Submission Format is automatically selected as 'eCTD'	



4	Enter the submission eCTD sequence number. This number should always be the next sequential number in the product lifecycle. Optionally enter any related sequence number to cross reference related submissions.	The sequence number is always a numeric value (range from 0000 to 9999)
5	Select the relevant 'PAM code' as provided in the PAM Submission Form **Please note:** the PAM submission form should be provided within the eCTD submission package in the same folder as the cover letter (EU M1 section 1.0)	PAM submission form is available here. More information on the use of PAM submission form can be found from the Post-Authorisation Guidance on PAMs – See 'How should I structure my PAM submission dossier'.

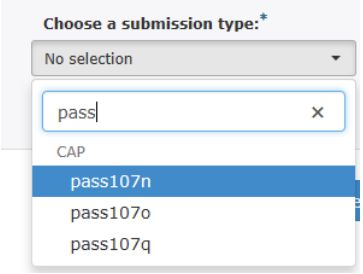
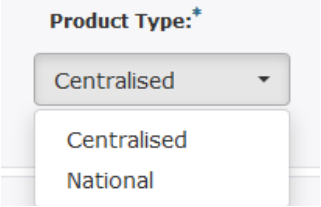
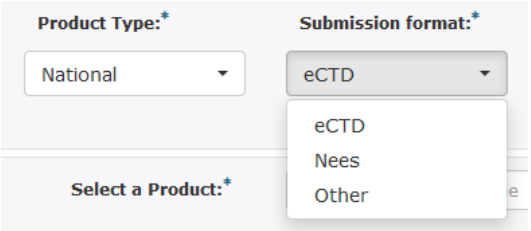


6	Search for the relevant product by typing any part of the product name in the 'Select a product' field. The more you type the more the list filtered.	It should be noted that the submissions cannot be 'grouped'. Each eCTD sequence will need to be submitted separately with its own delivery file.

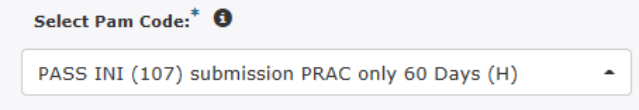


7	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

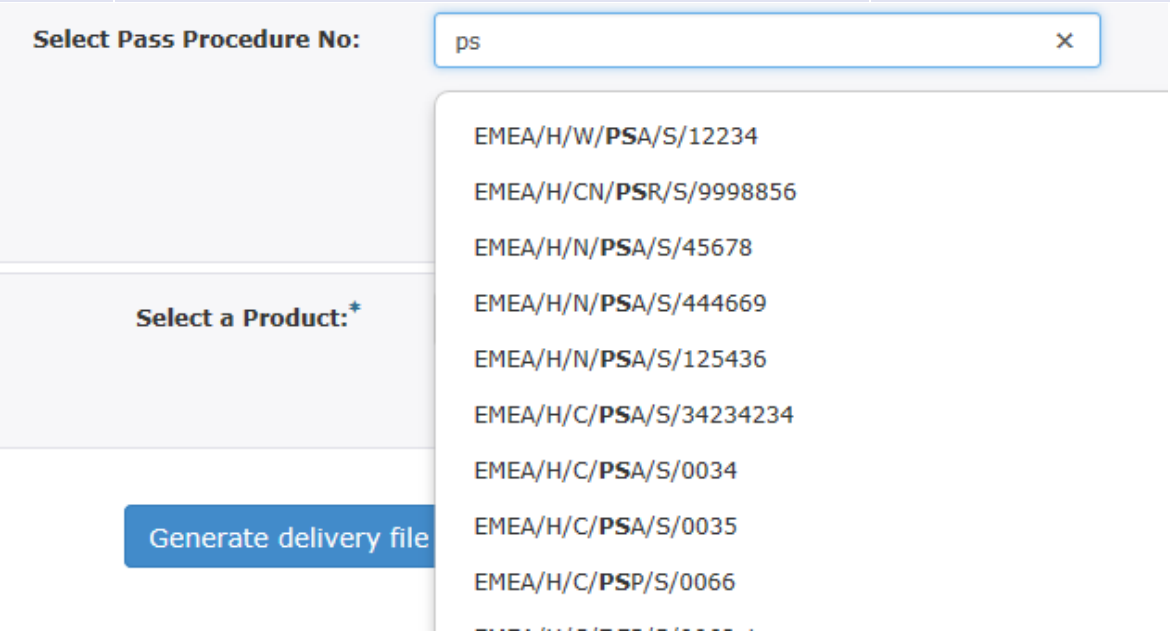
4.7. Create delivery file for PASS 107n, 107o and 107q submission for Nationally Authorised Products (human only)

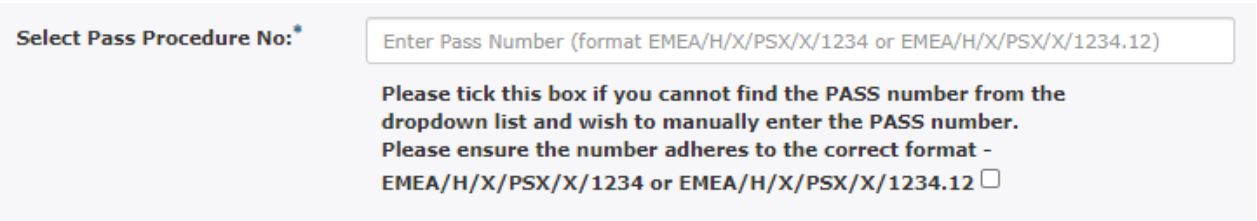
Step	Description	Notes
1	Select 'pass107n', 'pass107o' or 'pass107q' from the regulatory activities list (submission type). Select the 'submission-unit' from the list. This should in most cases be 'initial' or 'response'.	
		
2	As the PASS 107 submissions may contain either Centrally or Nationally Authorised products, it is important to ensure that the correct 'Product type' is selected from the dropdown menu.	
		
3	If Product type 'National' is selected the submission format also needs to be selected. Please ensure that you submit in the format that the product lifecycle is in the National Competent Authority, this should now be in most cases eCTD.	
		
4	Enter the submission eCTD sequence number. This number should always be the next sequential number in the product lifecycle. Optionally enter any related sequence number to cross reference related submissions.	The sequence number is always a numeric value (range from 0000 to 9999)
5	The relevant 'PAM code' is automatically selected when PASS 107n, 107o or 107q is selected	The system only allows selection of PAM codes that are relevant for PASS submissions. PAM submission form is available here. More information on the use of PAM submission form can

		be found from the Post-Authorisation Guidance on PAMs – See 'How should I structure my PAM submission dossier'. Please note that the PAM submission form should be provided within the eCTD submission package in the same folder as the cover letter (EU M1 section 1.0)



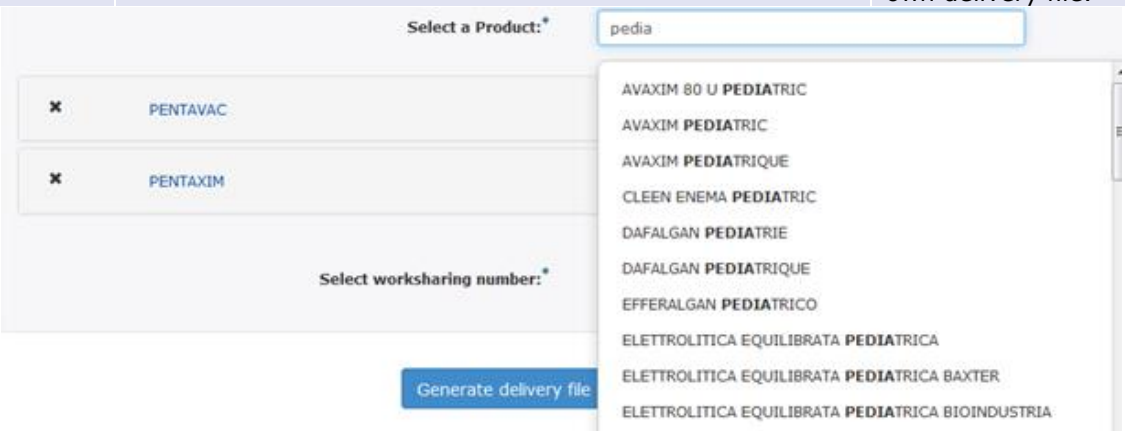
6	For non-initial submissions (validation-response, response etc), for NAPs only, the users should now select the relevant PASS Procedure number from the dropdown list. If the PASS number is not available from the list, please use the tick box to allow manual entry of the number.	An auto-complete textbox appears with the available procedure numbers retrieved from the database of FM_PASS FileMaker App





7	Search for the relevant product(s) by typing any part of the product name in the 'Select a product' field. The more you type the more the list filtered. The list of Nationally Authorised Products with retrieved from XEVDMP (Art. 57 database).	It is possible to select more than one product name from the list to ensure that all products and presentations are selected. It should be noted that the submissions cannot be

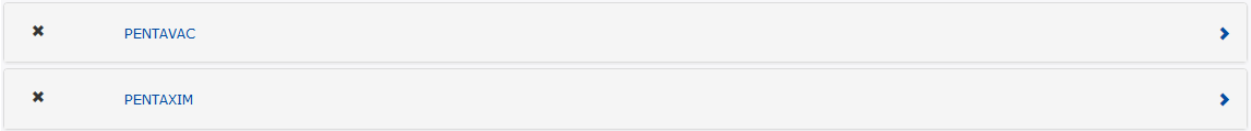
		'grouped' each eCTD or NeeS sequence will need to be submitted separately with its own delivery file.



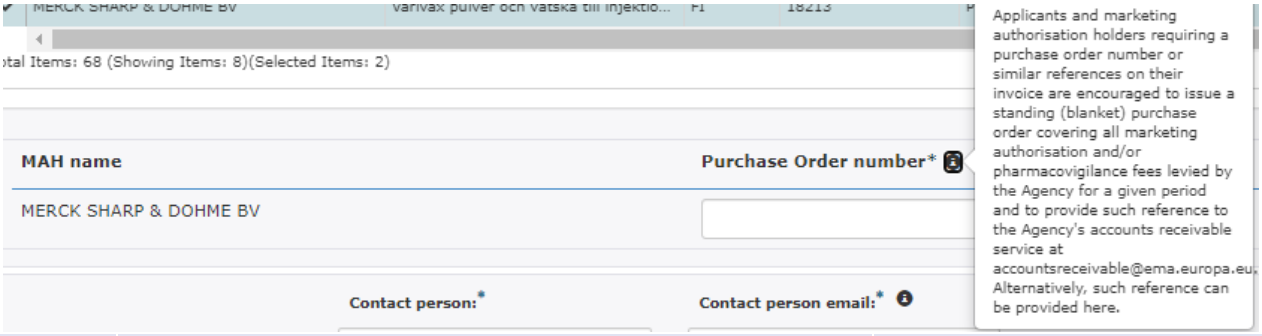
8	Expand the product details by clicking anywhere in the field with the selected product name and proceed to filter and select the relevant products/presentations. Multiple criteria may be used to filter the product selection.	The product EV code is now also available to help the selection of the correct product/presentation.

9	You can select all products/presentations by clicking to the field next to 'MAH name' field. Alternatively, click individual lines to select relevant products/presentations.	At least one of the products/presentation must be selected.

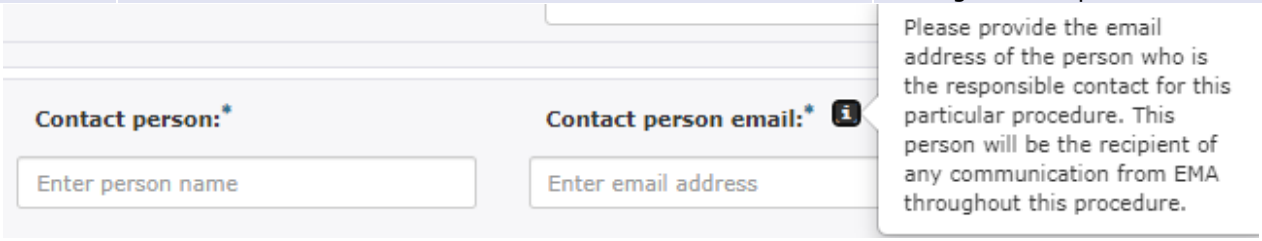
10	Close the selection by clicking anywhere in the field with the product name and repeat the previous step to include all products/presentations for which a single submission sequence has been prepared for.	



11	Users now must add the Purchase Order Number for each selected Marketing Authorisation Holder.	For Human submissions only. Applicable when Submission unit is "**initial**" and the Product type is "**National**



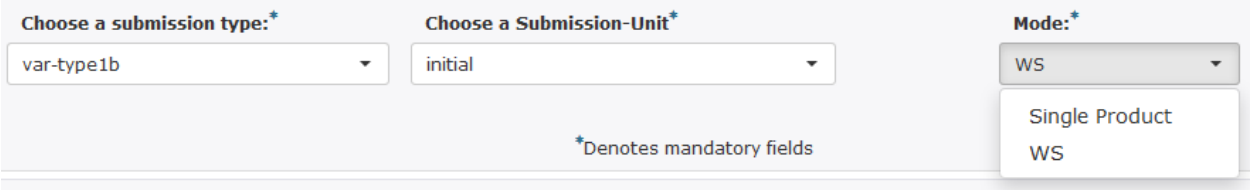
12	Please add the contact person name and email address in the mandatory fields	This person will be the recipient of any communication from EMA throughout the procedure.



13	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

4.8. Create delivery file for Medical Devices (human only)

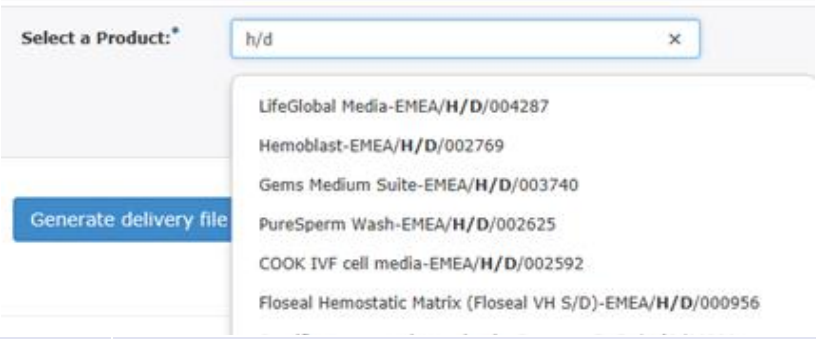
Step	Description	Notes
1	Select the relevant submission type from the regulatory activities list e.g. MAA or var-type2. Select the 'submission-unit' from the list.	



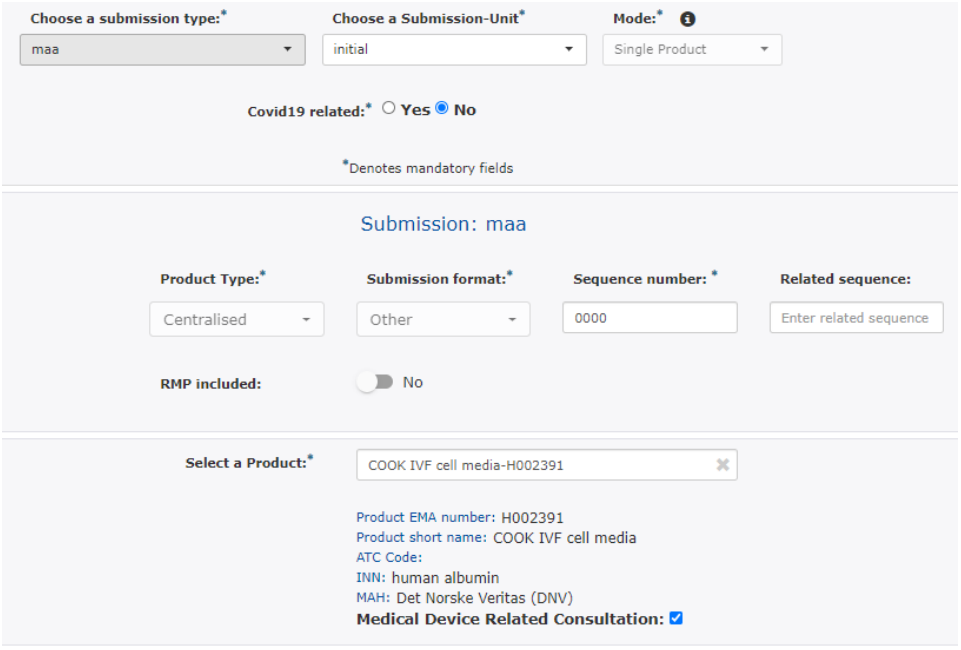
2	The Product type cannot be changed and must always be 'Centralised'. Please ignore 'submission format' **eCTD** when creating the delivery file for Medical device submissions. The system will **automatically** update this field to '**other**' once the medical device has been selected from the product selection menu. Enter the submission sequence number. This number should always be the next sequential number in the product lifecycle. For initial MAA submissions this is normally 0000. Optionally enter any related sequence number to cross reference related submissions. When creating delivery file for initial MAA submission for medical device, please indicate using a tick box that the product is a medical device. When creating the submission sequence for medical devices, it is important to name the 'sequence' using the same 'sequence' number as indicated in the delivery file even if the submission is in non-eCTD format.	Medical devices have EMA number EMEA/H/D/000123. The system will automatically change the submission format to 'other' when product with H/D product number is selected

Example: initial maa for Medical device

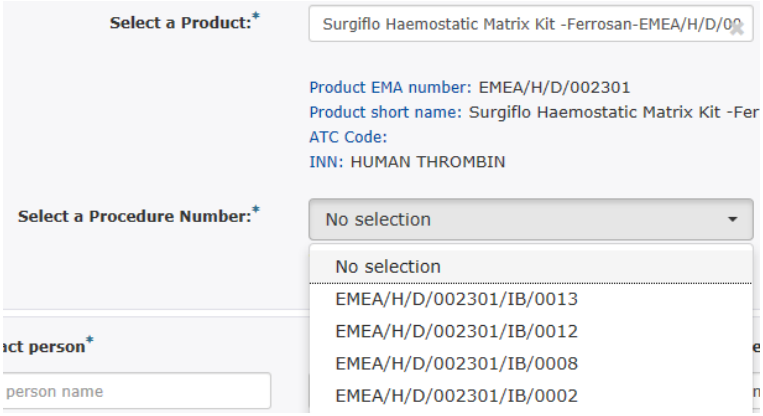
Example: delivery file for any subsequent submission for medical device



3	Once the product is selected or in case of initial maa submission, the tick box has been ticked, the 'submission format' automatically changes to 'other' to allow medical device format submission.	



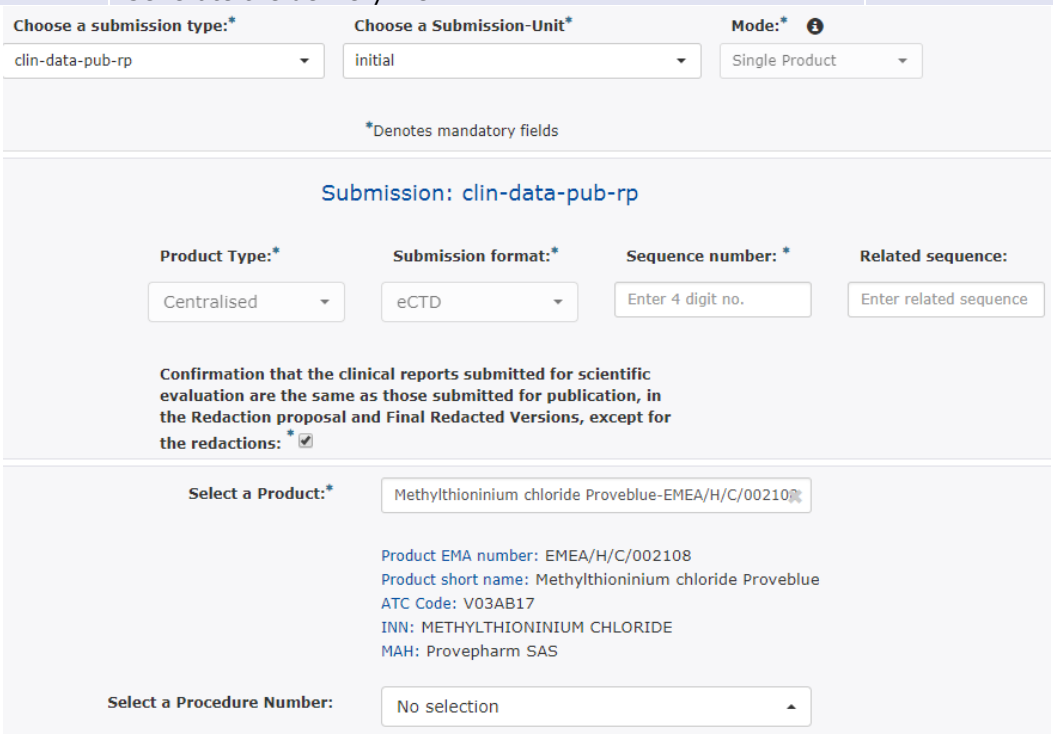
4	For post-authorisation activities, excluding the initial sequence for each post-authorisation procedure, please select the procedure number from the list of procedures	If you cannot find the procedure number from the list, please contact the EMA service desk for Human variations



5	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

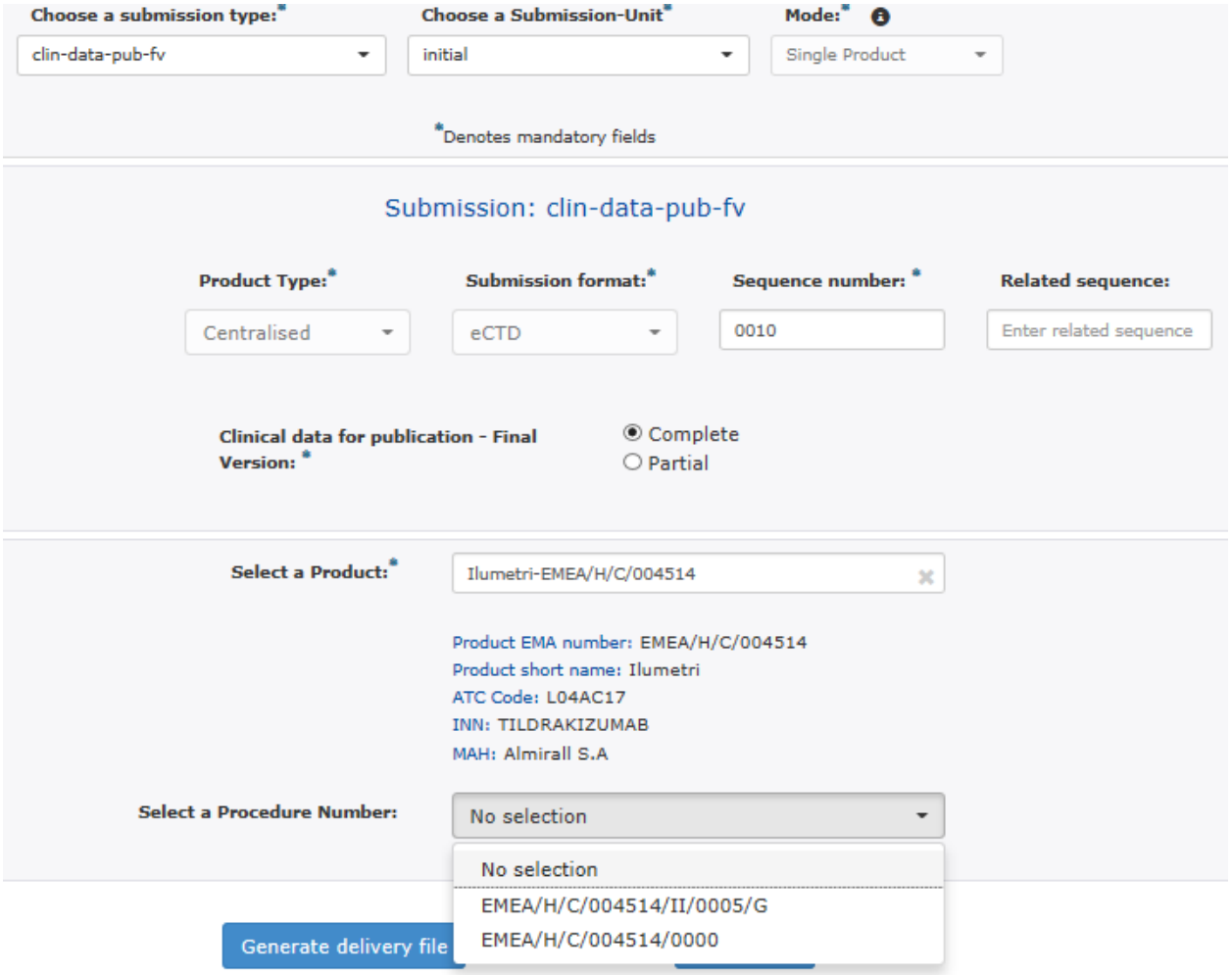
4.9. Clinical data publication redacted proposal (human only)

Step	Description	Notes
1	Select 'clin-data-pub-rp' from the regulatory activities list (submission type). The 'submission unit' initial is automatically selected and should not be changed. Mode is always 'single product' Product type is always 'centralised' and the submission format is always 'eCTD'. Relevant sequence number must be entered. Optionally enter any related sequence number to cross reference related submissions. Please indicate that the clinical reports submitted for evaluation are the same as those submitted for publication. This is a mandatory tick box. Select the relevant product. Select the appropriate procedure number from the predefined list. Generate the delivery file.	



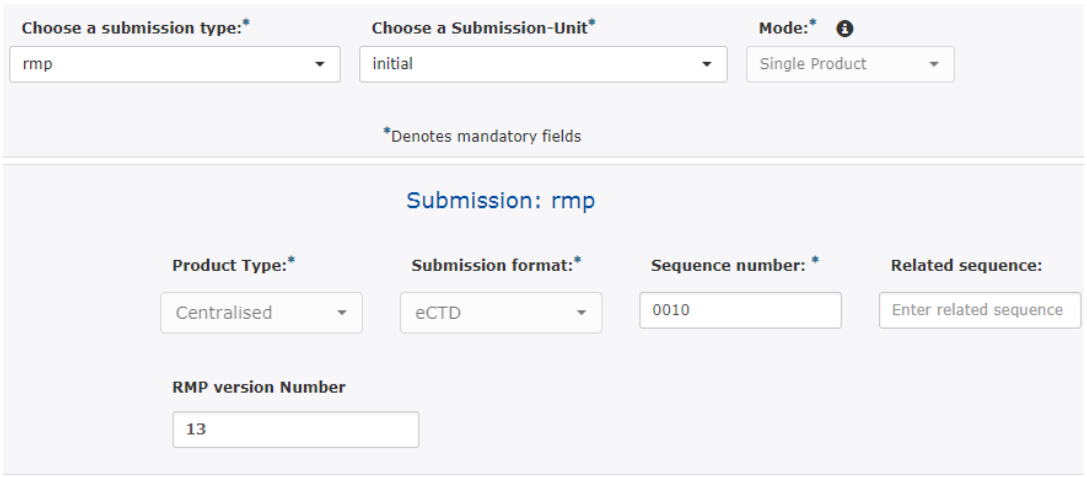
4.10. Clinical data publication final version (human only)

Step	Description	Notes
1	Select 'clin-data-pub-fv' from the regulatory activities list (submission type). The 'submission unit' initial is automatically selected and should not be changed. Mode is always 'single product' Product type is always 'centralised' and the submission format is always 'eCTD'. Relevant sequence number must be entered. Optionally enter any related sequence number to cross reference related submissions. Please indicate if the final version is complete or partial using the mandatory selection. A partial "Final Redacted Version" package, where the documents are redacted according to the applicant/MAH views may be submitted where an agreement with EMA wasn't reached and the applicant decided to apply for interim relief against an EMA decision to publish the documents without accepting the redactions which are still controversial. The applicant will confirm, in the text of the cover letter, which redactions (page, line) have been made. In the event that interim relief is sought against the EMA decision, the EMA will publish the partial "Final Redacted Version". When a final decision is issued, the applicant shall submit a "Final Redacted Version". Select the relevant product. Select the appropriate procedure number from the predefined list. Generate the delivery file.	'Partial' final version should only be submitted in exceptional situations.


Choose a submission type:*
clin-data-pub-fv
Choose a Submission-Unit*
initial
Mode:*
Single Product
*Denotes mandatory fields
Submission: clin-data-pub-fv
Product Type:*
Centralised
Submission format:*
eCTD
Sequence number:*
0010
Related sequence:
Enter related sequence
Clinical data for publication - Final Version:*
Complete
Partial
Select a Product:*
Ilumetri-EMEA/H/C/004514
Product EMA number: EMEA/H/C/004514
Product short name: Ilumetri
ATC Code: L04AC17
INN: TILDRAKIZUMAB
MAH: Almirall S.A
Select a Procedure Number:
No selection
No selection
EMEA/H/C/004514/II/0005/G
EMEA/H/C/004514/0000
Generate delivery file

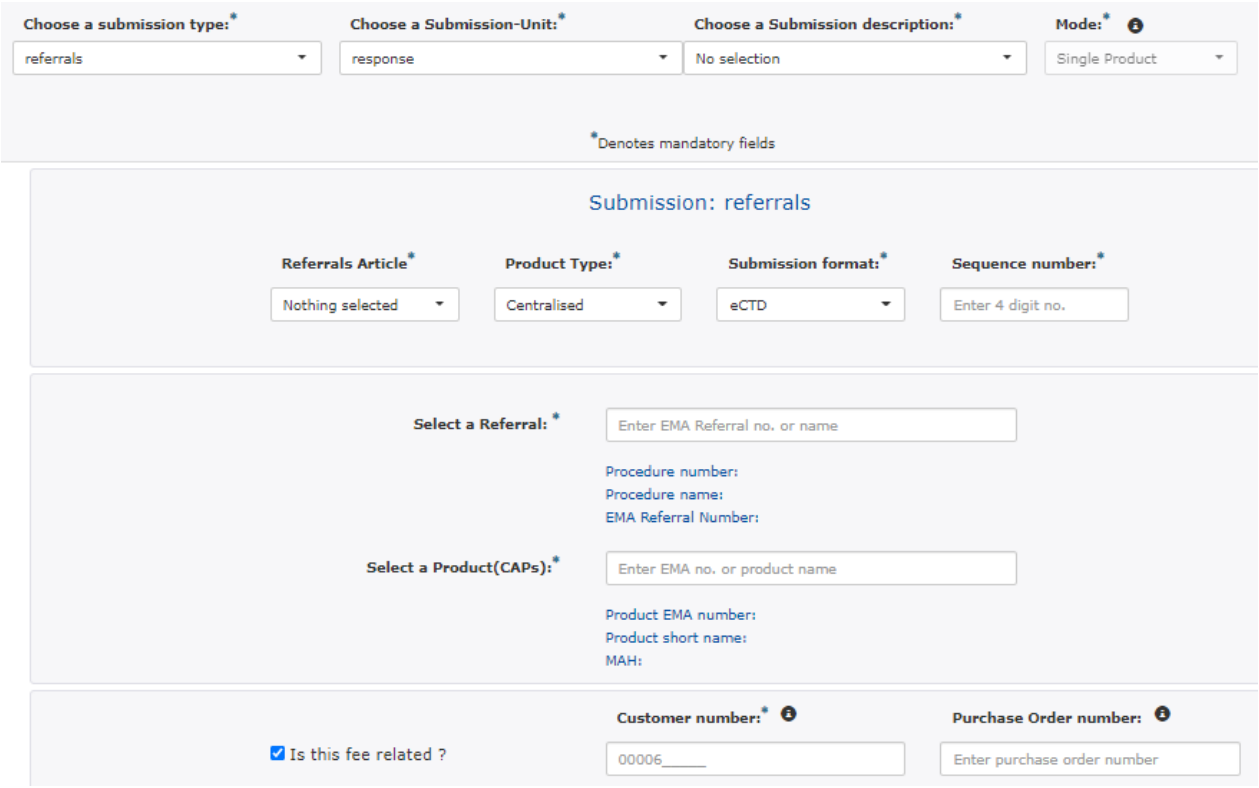
4.11. Risk Management Plan (RMP) (human only)

Step	Description	Notes
1	Select 'rmp' from the regulatory activities list (submission type). Please select the relevant 'submission unit' from the list. Mode is always 'single product' Product type is always 'centralised' and the submission format is always 'eCTD'. Relevant sequence number must be entered. Optionally enter any related sequence number to cross reference related submissions. Please provide the RMP version number for example 2.0 or 13. Please select the product and generate the delivery file. It should be noted that users can also identify whether a Risk Management Plan is included for the following type of submissions: MAA; Variation Type IA; Variation Type IAIN; Variation Type IB; Variation Type II; Extension; PAM; Renewal	



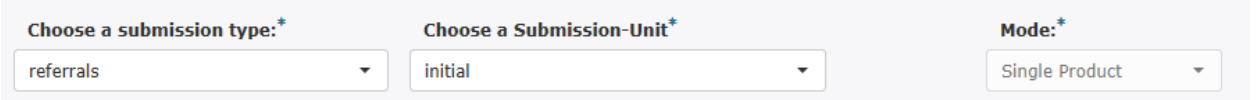
5. Create delivery file screen – Referrals

Referrals containing products for **Human** Use only: EMA is working to include the information currently provided in the Referral cover letter in to the XML delivery file to remove the need for a separate cover letter in future. The Contact person details, customer number and purchase order number fields for fee related referrals are now included in the XML delivery file. This approach will be further expanded for other procedure types with intention to remove the use of the Formatted Table Template.
This change is **not** applicable to Veterinary referrals.

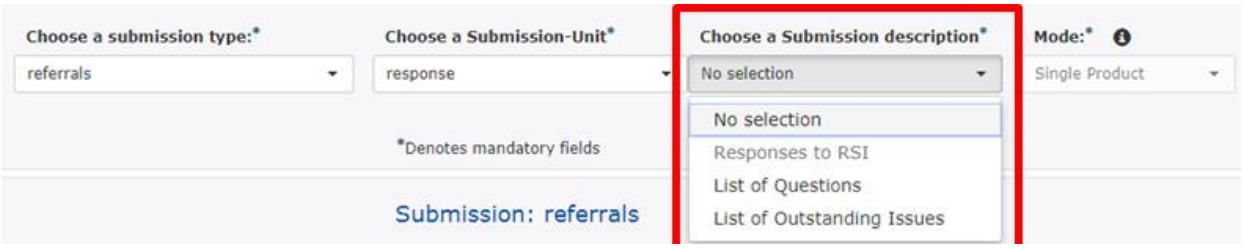


5.1. Create delivery file for Referrals reviewed by the CHMP containing Centrally Authorised Products (CAPs) – Art. 20 and Articles 5(3), 31 and 107i

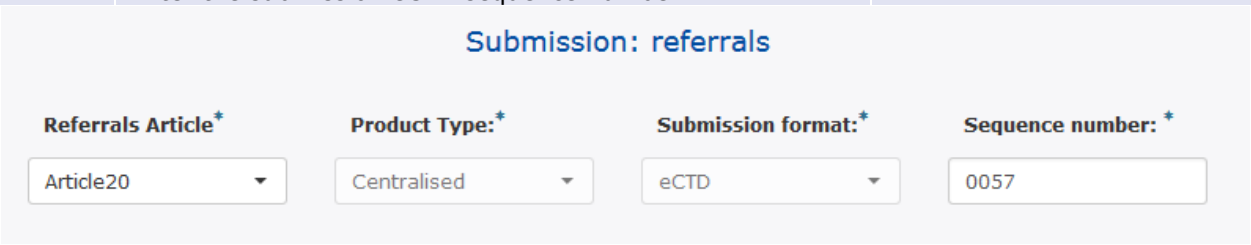
Step	Description	Notes
1	Select Submission type 'Referrals' Select the 'submission-unit' from the list. The submission mode is always single product.	



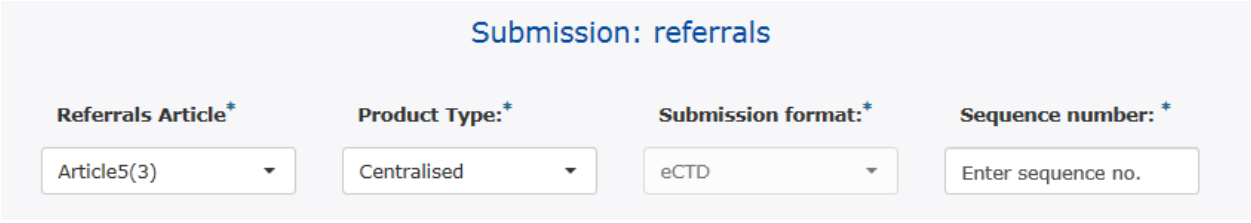
1.1	If submission unit is "response", then indicate the type of response by selecting a value from the submission description	For both Human & Veterinary submissions



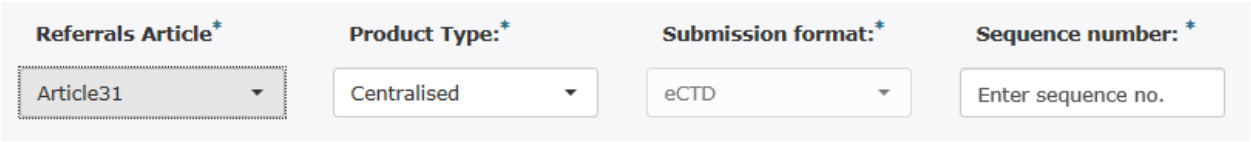
2	If you select Article20 from the dropdown list. The Product type and the submission format cannot be changed and must always be 'Centralised' and 'eCTD'. Enter the submission eCTD sequence number.	The sequence number is always a numeric value (range from 0000 to 9999)



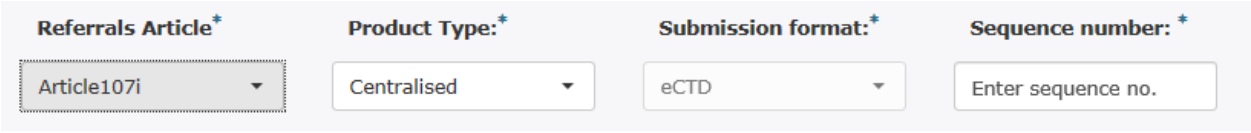
3	If you are selecting Article5(3), Article31 or Article107i from the dropdown list, select the procedure type 'Centralised'. If Centralised is selected the submission format cannot be changed and must always be 'eCTD'. Enter the submission eCTD sequence number.	The sequence number is always a numeric value (range from 0000 to 9999)



Or

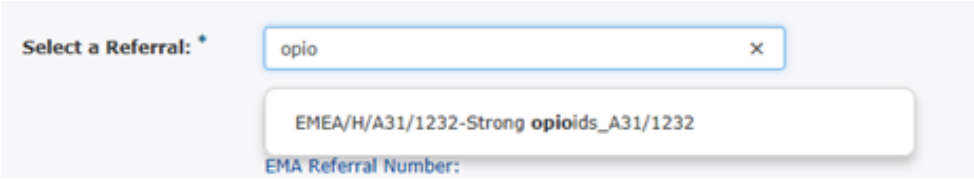


Or

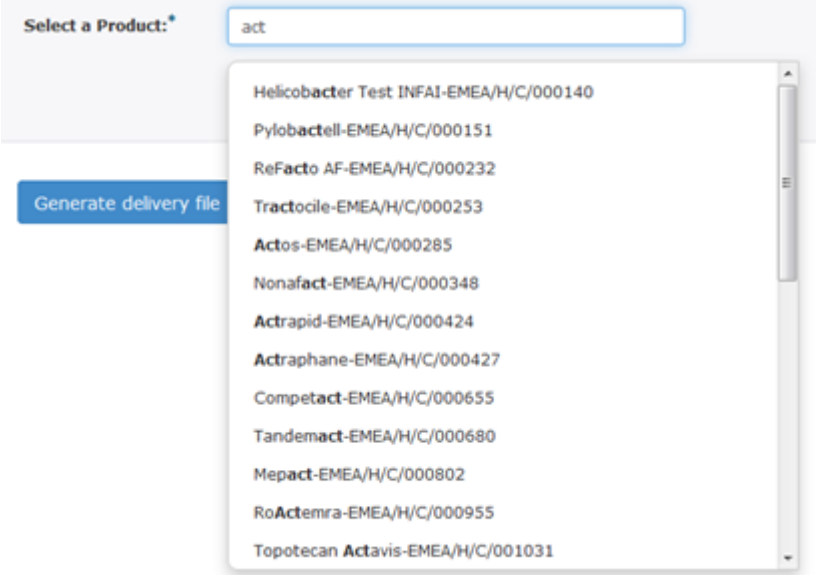


4	Select the referral procedure by typing the article, the referral number or the product/active substance name. The more you type the more the selection is filtered. Avoid using dash (-) in the search field.	Please note that the search does not recognise dash (-) symbol. Please search using the referral number for example 1234.

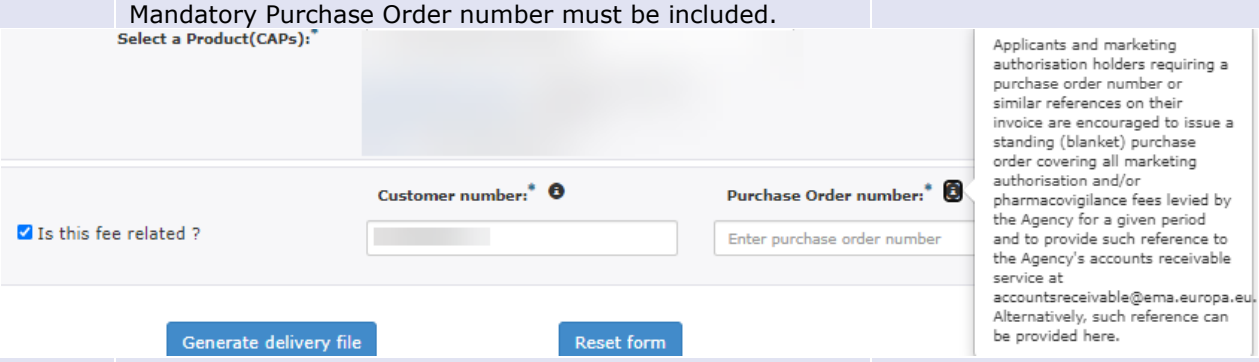
or



5	Search for the relevant product by typing any part of the product name or EMEA product number in the 'Select product' field. The more you type the more the list filtered.	



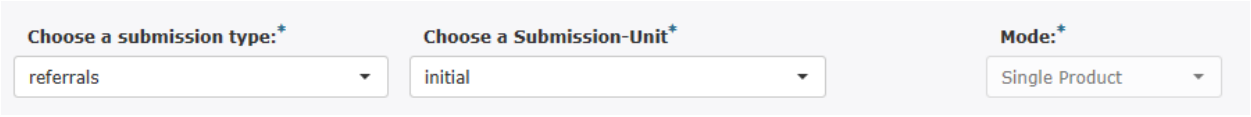
6	If the referral procedure is fee related, please tick the box 'Is this fee related?' to expand the section. The Customer number is prefilled using the MAH customer number from EMA product database; however, it can be manually changed if it is incorrect. Mandatory Purchase Order number must be included.	Please include the SAP Customer Number and purchase order number if applicable for fee related Referral procedures.



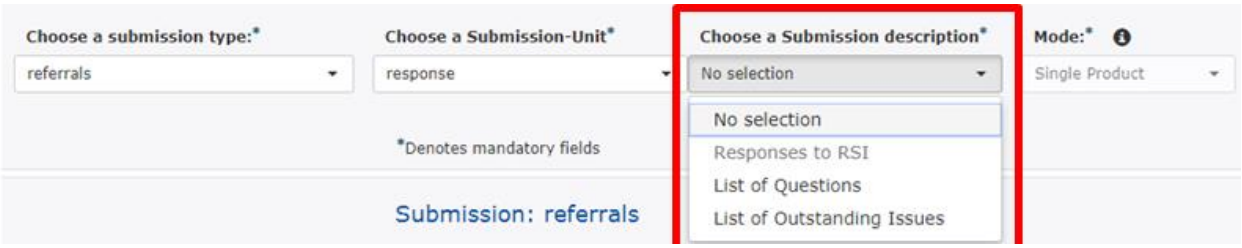
7	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

5.2. Create delivery file for Referrals reviewed by the CHMP containing Nationally Authorised Products (NAPs) – Articles 5(3), 31, 107i and Articles 13, 16C-1-C, 16-C-4, 29(4), 30 and 29 Paediatric

Step	Description	Notes
1	Select Submission type 'Referrals' Select the 'submission-unit' from the list. The submission mode is always single product.	

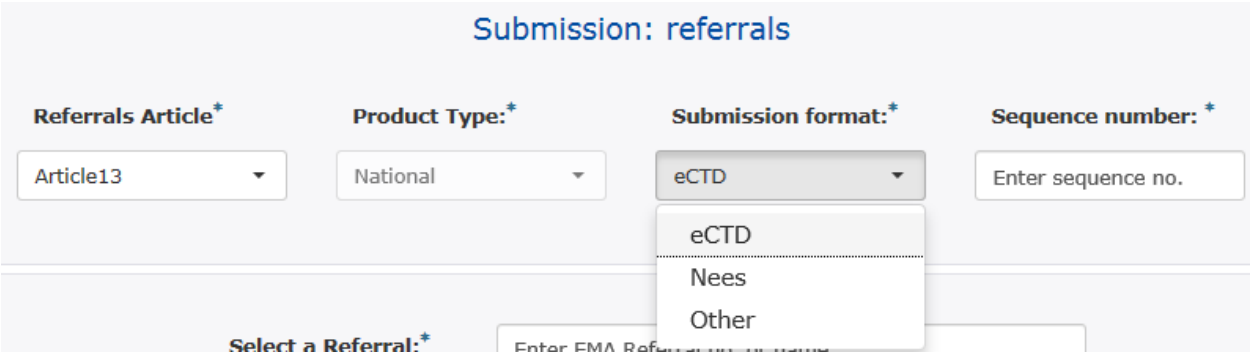


1.1	If submission unit is "response", then indicate the type of response by selecting a value from the submission description	For both Human & Veterinary submissions



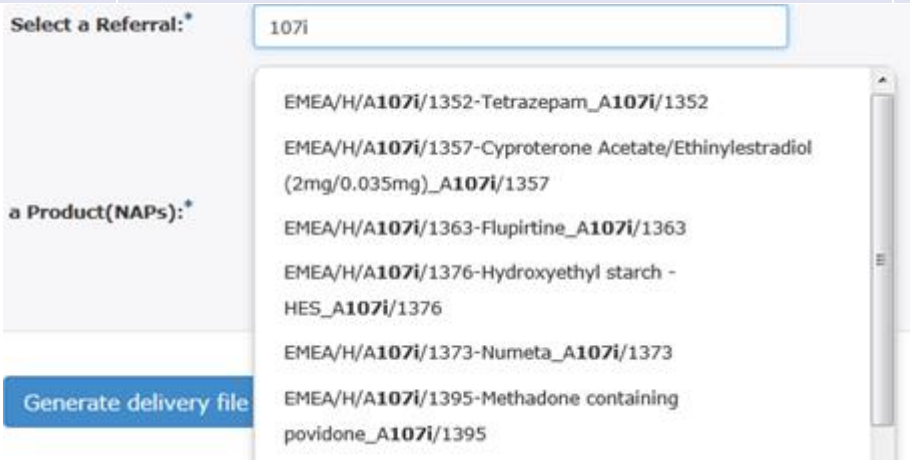
2	Select the relevant article (5(3), 31 or 107i Select the 'Product type' National from the dropdown list. The submission format may be changed to eCTD, NeeS or Other	

3	If you select Articles 13, 16C-1-C, 16-C-4, 29(4), 30 or 29 Paediatric) from the dropdown list the product type is always 'National' for these procedures. The submission format may be changed to eCTD, NeeS or Other	

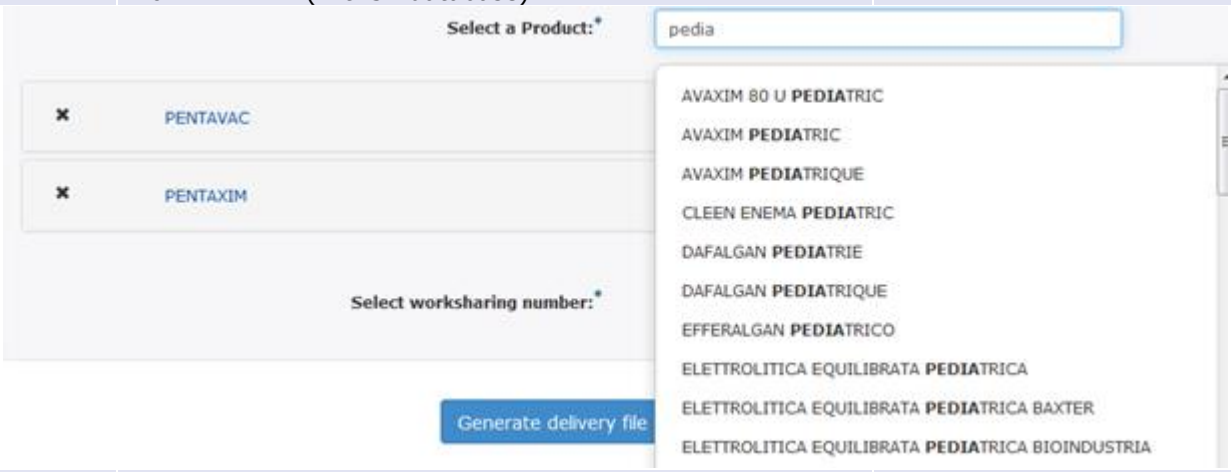


4	Enter the submission sequence number. This number should always be the next sequential number in the product	

	lifecycle. If the submission is in 'other' format you may enter 0000 in the sequence number field	
5	Select the correct referral procedure number by typing the article, the referral number or the product/active substance name. The more you type the more the selection is filtered. Avoid using dash (-) in the search field.	Please note that the search does not recognise dash (-) symbol. Please search using the referral number for example 1234.



6	Search for the relevant product(s) by typing any part of the product name in the 'Select a product' field. The more you type the more the list filtered. The list of Nationally Authorised Products with retrieved from XEVDMP (Art. 57 database).	It is possible to select more than one product name from the list to ensure that all products and presentations are selected.

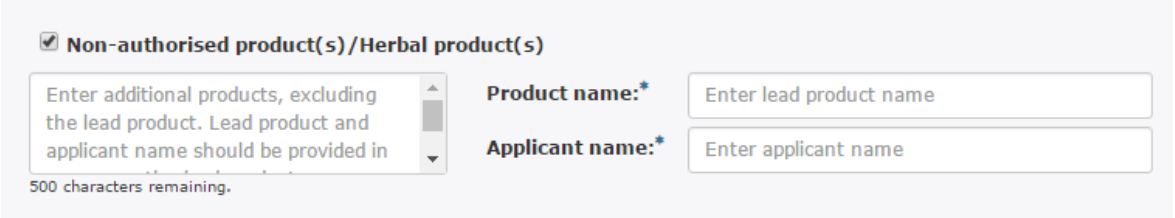


7	Expand the product details by clicking anywhere in the field with the selected product name and proceed to filter and select the relevant products/presentations. Multiple criteria may be used to filter the product selection.	

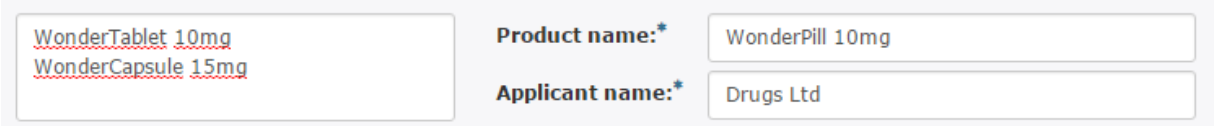
8	You can select all products/presentations by clicking to the field next to 'MAH name' field. Alternatively, click individual lines to select relevant products/presentations.	At least one of the products/presentation must be selected.

9	Close the selection by clicking anywhere in the field with the product name and repeat the previous step to include all products/presentations for which a single submission sequence has been prepared for.	

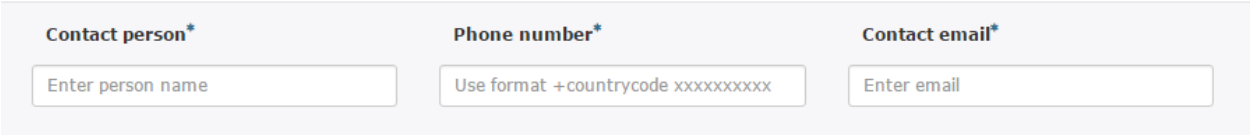
10	If the procedure contains non-authorised product(s) or herbal product(s) tick the box and provide a single 'lead' product name in the 'Product name' field and the applicant/company name in the 'Applicant name' field. If multiple products are included, the product details for the additional products can be included in the free text field	**Note:** Do not duplicate/repeat the 'lead' product details in the free text field if they are already entered in the Product name field. **Note:** If any authorised products are included in the same delivery file, please do not provide Lead product details. The 'first' NAP included in the delivery file will be considered as the 'lead' product.



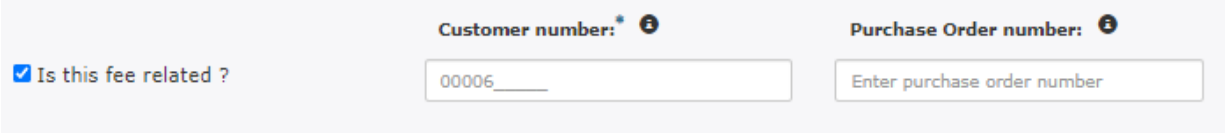
Example:



11	Provide the contact person details for the referral.	**Note:** Please provide the contact details for the contact person during the referral procedure



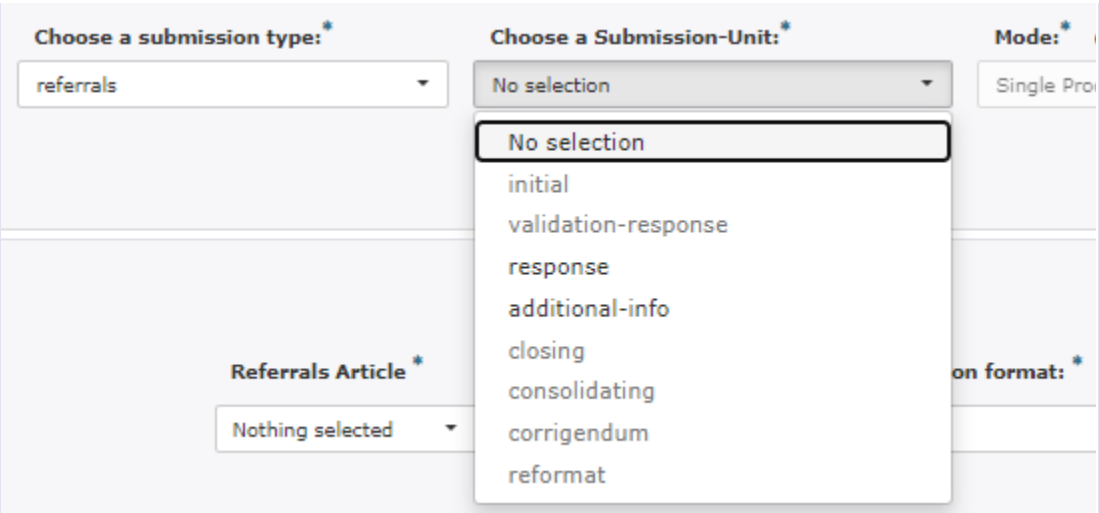
12	If the referral procedure is fee related, please tick the box 'Is this fee related?' to expand the section. Please provide the EMA SAP Customer number and the purchase order number	



13	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

5.3. Create delivery file for Veterinary Referrals reviewed by the CVMP[1] for Centrally or Nationally Authorised Products

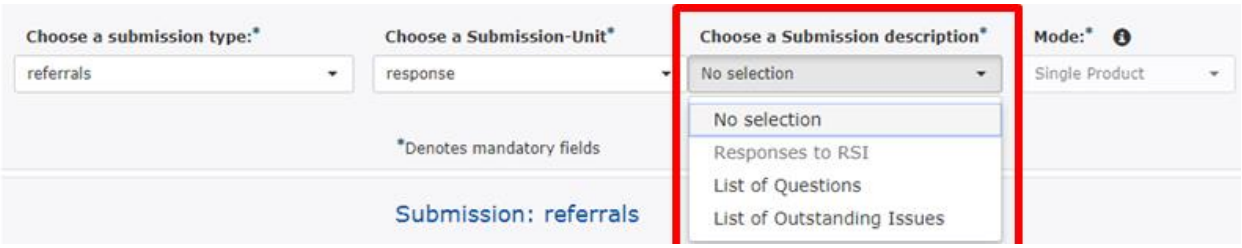
Step	Description	Notes
1	Click on the 'Veterinary' button to enter the vet submissions domain. Select Submission type 'referrals'. Select the 'submission-unit' from the list. Select relevant submission-unit i.e. response or additional-information. The submission mode is disabled and shows always 'Single product.'	In most cases, the first referral package submitted by a MAH is a response to a referral list of questions. For this purpose submission-unit 'response' should be used.



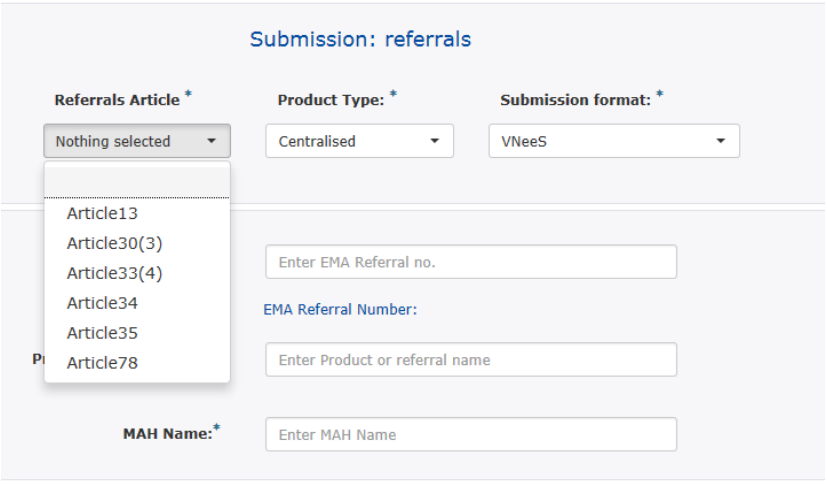
If submission unit is "response", then indicate the type of response by selecting a value from the submission description

[1] Committee for Medicinal Products for Veterinary Use. For more information concerning referrals reviewed by the CVMP, see the Veterinary Regulatory Referral Guide.

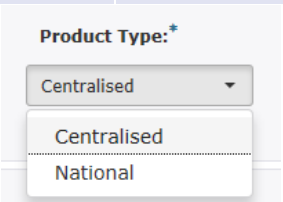
	1.1	



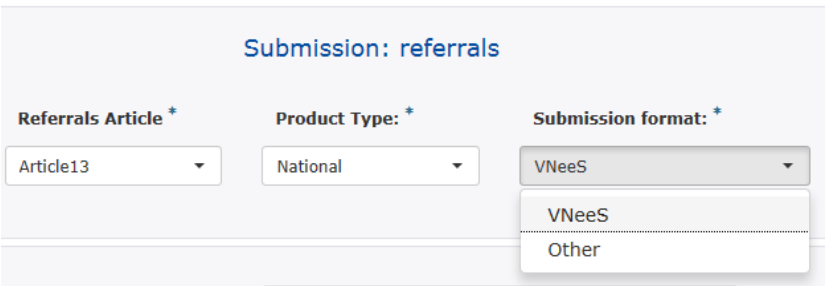
2	Select Referral Article from the dropdown list. The system will only allow selection of a Product Type that is relevant for the selected Referral Article as follows: • Article 13 -> National (only) • Article 30(3)-> Centralised or National • Article 33(4) -> National (only) • Article 34 -> National (only) • Article 35 -> National (only) • Article 78 -> National (only)	• Note that Article 45 procedure submissions should now be submitted following the steps described in point 4.1.1. Create delivery file.



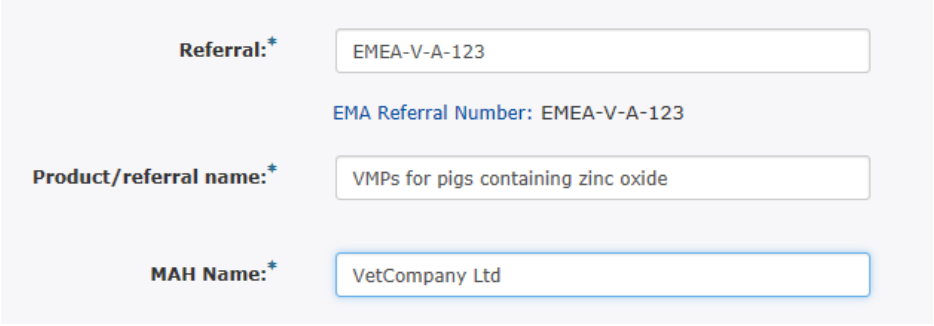
3	Select Product type from the dropdown list in accordance with the status of the product to which your submission relates. This can either be 'Centralised' or 'National'.	Please note that for multiple product submissions you will not be able to change the mode 'single product'. The submission will be accepted despite this limitation.



4	Select Submission format from the dropdown. This can either be 'VNeeS' or 'Other'.	If CTD is used for part II of a VMP dossier, the submission format to select is "VNeeS".



5	In the Referral field, **enter** the specific referral number assigned to this procedure. This is a 3 digit number in format: EMEA-V-A-123.	Enter the three digits in the **number** field.
6	In the Product/referral name field, **enter** the specific name assigned to this procedure. This name can be found on the letter from the Agency regarding the Start of the procedure and a List of Questions (eg. 'VMPs for pigs containing zinc oxide'').	Enter the product or referral name in the **free text** field.
7	In the MAH Name field **enter** the name of the marketing authorisation holder of the product to which the submission relates.	Enter the MAH name in the **free text** field.



8	Confirm the details are correct. Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

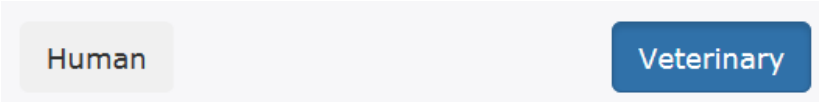
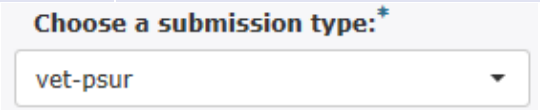
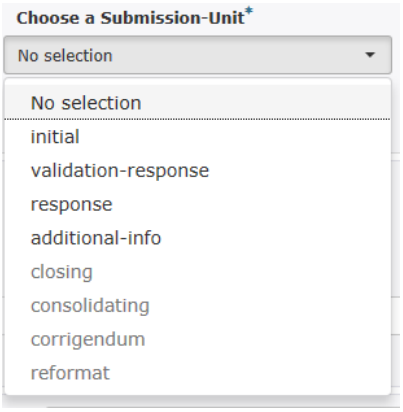
6. Create delivery file screen PSUR (Periodic Safety Update Report)

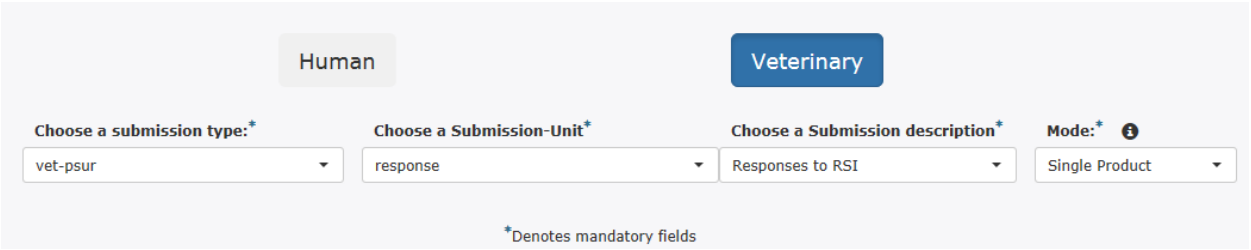
6.1. Create delivery file for human PSUR submissions

Note: Please note that all Human PSUR submissions, included in the EU PSUR Single Assessment (PSUSA) or outside the single assessment (non-EU PSUR single assessment) should be submitted to the PSUR Repository. The only exception to this is PSURs for products authorised under Art. 58 (WHO). For PSUR submissions for product authorised under Article 58 (WHO) follow instructions in section 4. Create delivery file scree Centralised Procedure.

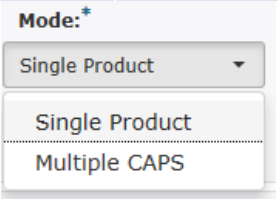
For all other PSUR/PSUSA submissions for Human products, select PSUR/PSUSA from the dropdown menu and the system automatically takes the user to the XML delivery file creation screen for PSUR submissions (for submissions to the PSUR Repository). More information on the Human PSUR/PSUSA submissions can be found from the PSUR Repository website.

6.2. Create delivery file for veterinary PSUR submissions

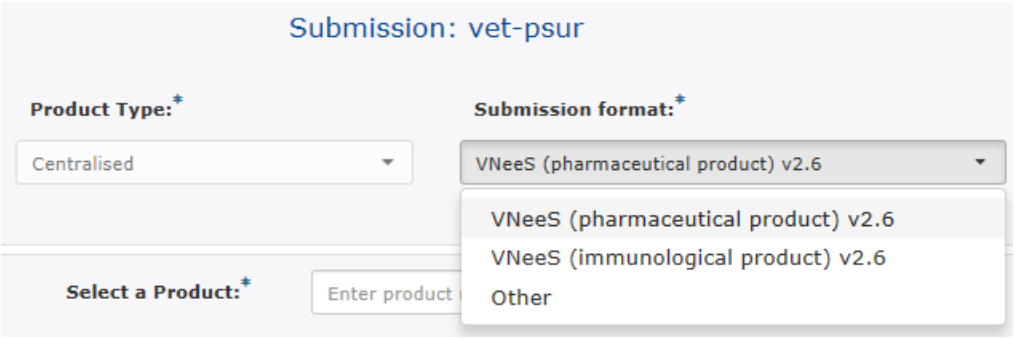
Step	Description	Notes
1.	Select Domain 'Veterinary'	
		
2.	Select Submission type 'vet-PSUR'	
		
3.	Select relevant Submission-Unit in accordance with the definitions given on page 9 and 10 of this document. Note that not all types of submission-unit may be applicable to PSURs and hence some will have been disabled and cannot be used.	Submission-unit 'initial' should be used in case of submitting a particular PSUR to the Agency for the first time. For responses, select 'response'. In case the submission unit is 'response' submission description 'Responses to RSI' is automatically selected.
		



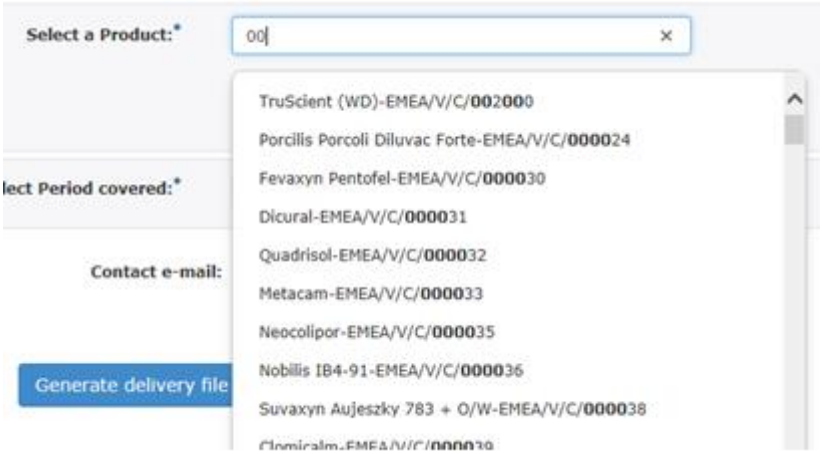
4.	Select the 'Mode' • Single • Multiple CAPS	For submission of multiple CAPs from 1 January 2018, a separate XML delivery file must be created and a separate submission made for each of the CAP included in the procedure. An identical package covering all relevant products should be submitted for each, with only the XML delivery file changing for each product. Note however that such submissions must be pre-agreed with EMA beforehand.



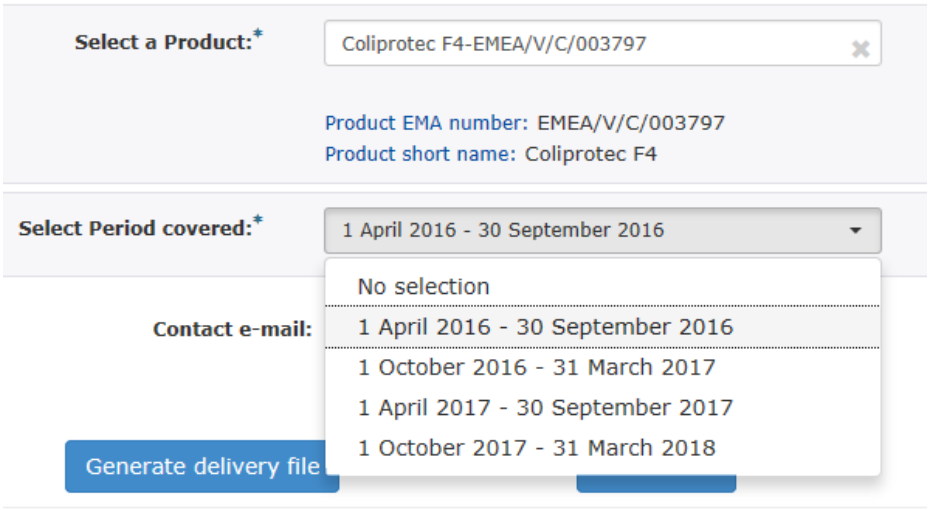
5.	The Product type cannot be changed and must always be 'Centralised'. The submission format may be chosen from the following options:	



6.	Search for the product by typing any part of the product name or EMEA product number in the 'Select product' field. The more you type the more the list is filtered.	Enter the name of the CAP for Single or 'lead' CAP for procedure that contains multiple CAPs



7.	Select 'Period Covered' by selecting the correct date range from the dropdown menu. You can only submit a PSUR when one is due and the date range is available in the user interface.	If you have been requested to submit a PSUR but cannot find the 'period covered' in the system, please contact vet.applications@ema.europa.eu.

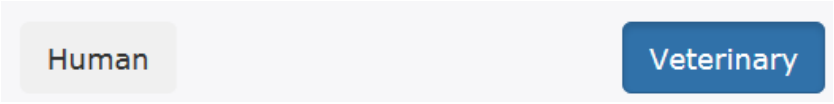
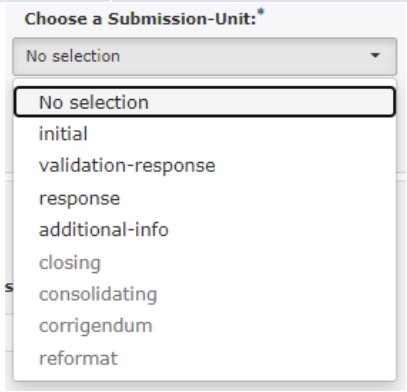


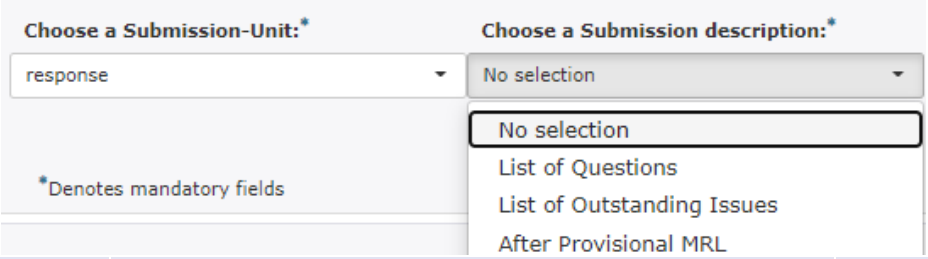
8.	Provide contact email address if the sender is different from the QQPV. This email address will be used for all communication between the MAH and the EMA regarding this PSUR Procedure.	If the PSUR is submitted by the QPPV, please leave this field empty.

9.	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

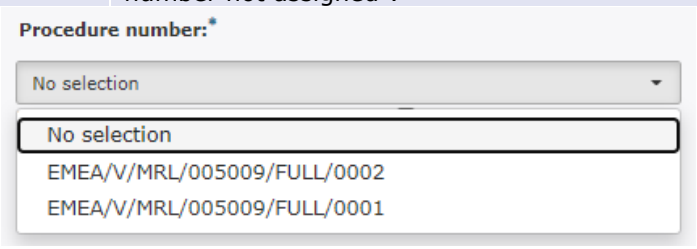
7. Create delivery file screen – Maximum Residue Limit (MRL) applications (veterinary only)

7.1. Create delivery file for MRL submissions

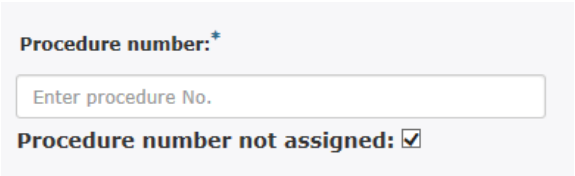
Step	Description	Notes
1	Select Domain 'Veterinary'	
		
2	Select Submission type in accordance with definitions presented on page 8 and 9 of this document: mrl-extension mrl-extrapolation mrl-full mrl-modification	
		
3	Select relevant Submission-Unit in accordance with definitions presented on page 9 and 10 of this document. Note that not all types of submission-unit may be applicable to MRLs and hence some will have been disabled and cannot be used.	Submission-unit 'initial' should be used always when submitting any of the MRL types to the Agency for the first time. For responses, select 'response'.
		
	For response submissions, please select the relevant Submission description from the dropdown list	



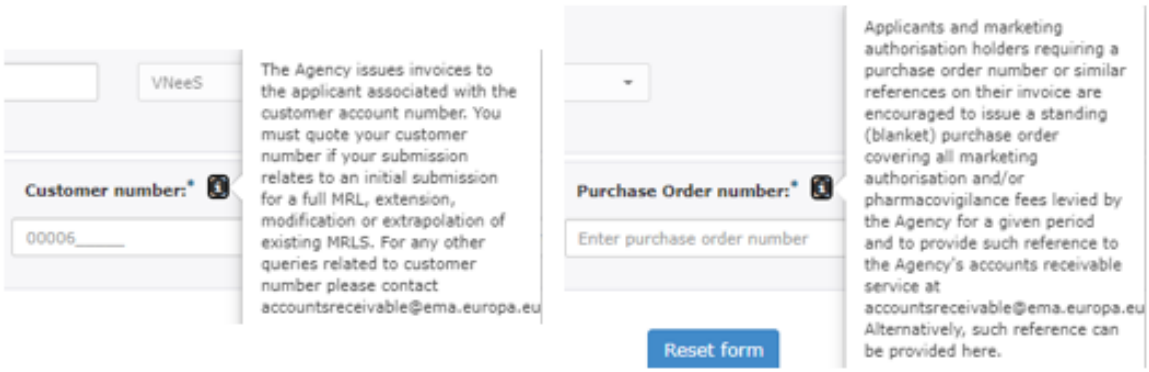
5	Select the substance by typing the name in field and selecting from the list of available substances	If you are unable to find the substance, please contact vet.applications@ema.europa.eu
6	For MRLs the Submission Format is always VNeeS. This field is automatically filled and cannot be changed by the user.	
7	Select the relevant Procedure number by typing any part of the procedure number in the field and select the relevant procedure. In case the Submission-unit is 'initial', the procedure number is not yet available. Please tick "Procedure number not assigned".	



or

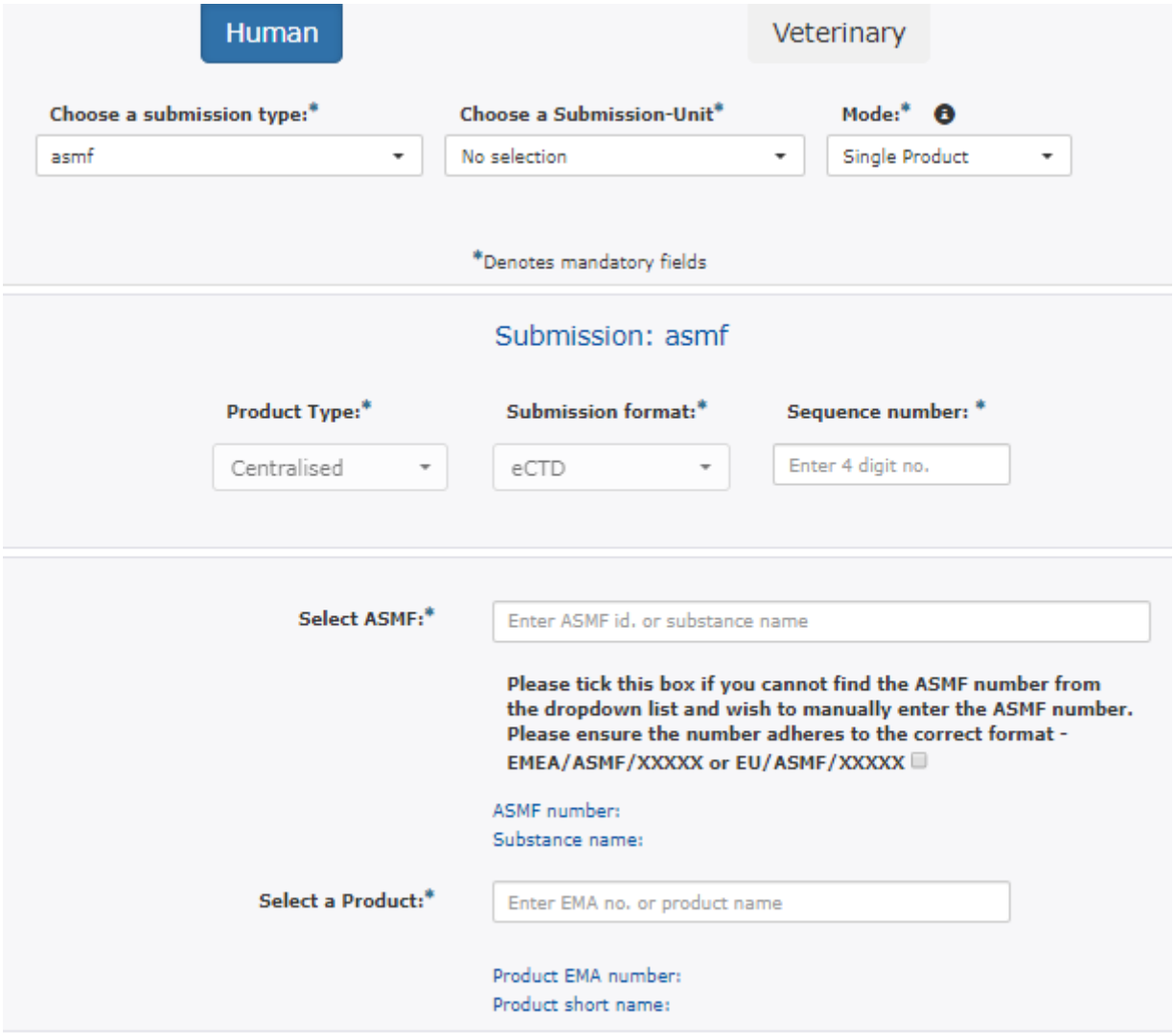


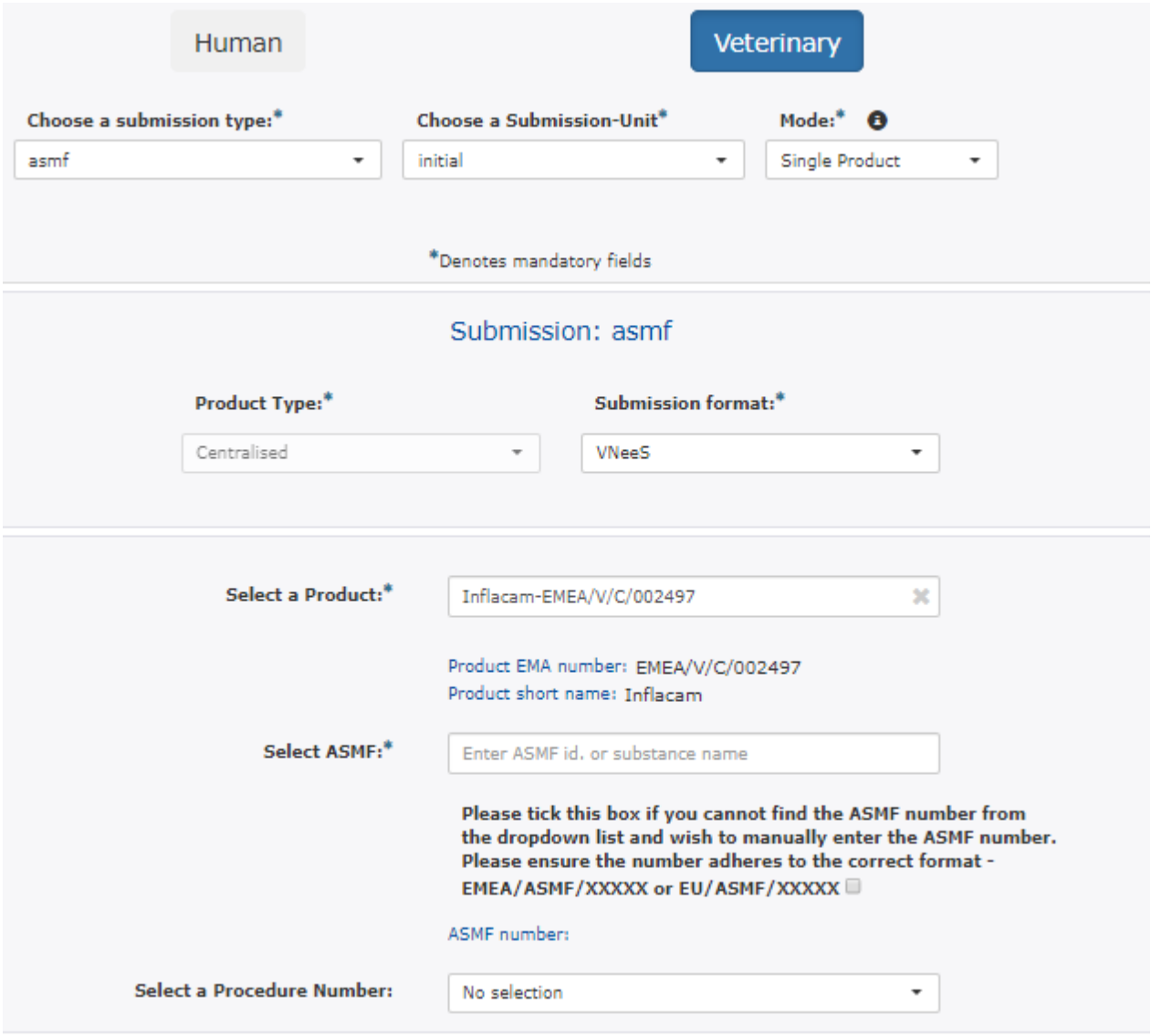
8	For submission unit 'initial' Customer number and Purchase Order number are mandatory fields	



9	Confirm the details are correct. Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

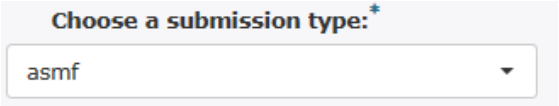
8. Create delivery file screen – ASMF



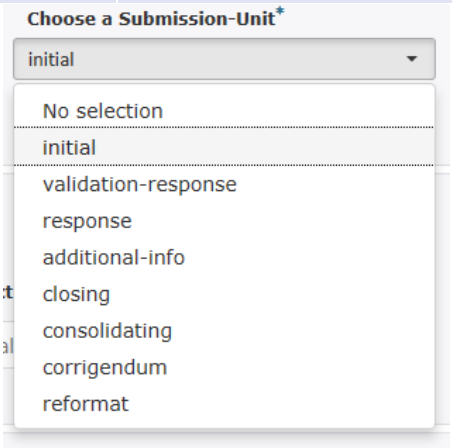


8.1. Create delivery file for ASMF

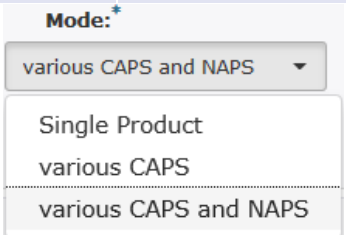
Note: Please note that there are some issues with ASMF number availability for limited number of ASMF procedures. If you are unable to find the ASMF number from the list you can manually enter the ASMF number if you tick the box to indicate .

Step	Description	Notes
1	Select Submission type 'ASMF'	
		
2	Select relevant Submission-Unit	Submission-unit 'initial' should be used both in case of submitting an ASMF to the Agency for the first time, as well as when submitting an updated version of an ASMF

		already held by the Agency (within the context of starting a variation procedure).

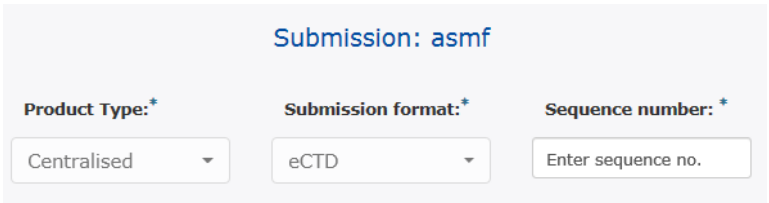


3	Select the 'Mode' • Single • Various CAPs • Various CAPs and NAPs	

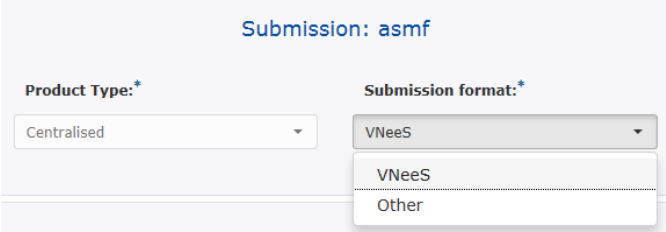


4	**Human domain:** The Product type and the submission format cannot be changed and must always be 'Centralised' and 'eCTD'. Enter the submission eCTD sequence number. **Veterinary domain:** The Product type cannot be changed and must always be 'Centralised'. The submission format may be chosen from the two options: 'VNeeS' or 'Other'.	The sequence number is always a numeric value (range from 0000 to 9999) Select 'Other' for ASMFs in CTD structure.

Human ASMF opions:



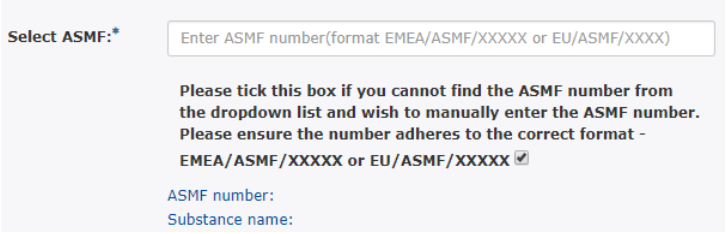
Veterinary ASMF opions:



5	Select the ASMF procedure by typing the EU or EMEA ASMF number or the active substance name. The more you type the more the list is filtered. The easiest way to search is by typing just the numbers without EU or EMA prefix and then selecting the correct ASMF number from the list. If users are unable to find the appropriate ASMF procedure number from the predefined list they can manually enter the ASMF number by ticking the box. Please ensure that the number is in the correct format.	The ASMF holder should request and Agency ASMF reference number from the EMA service desk up to two weeks before submitting a complete ASMF, or an update to an already submitted ASMF. For Veterinary ASMF submissions the product selection is before the ASMF procedure selection due to data protection reasons. For Veterinary ASMF procedures for unauthorised products, only the ASMF procedure number without the active substance is shown.

ASMF Selection from Predefined List:

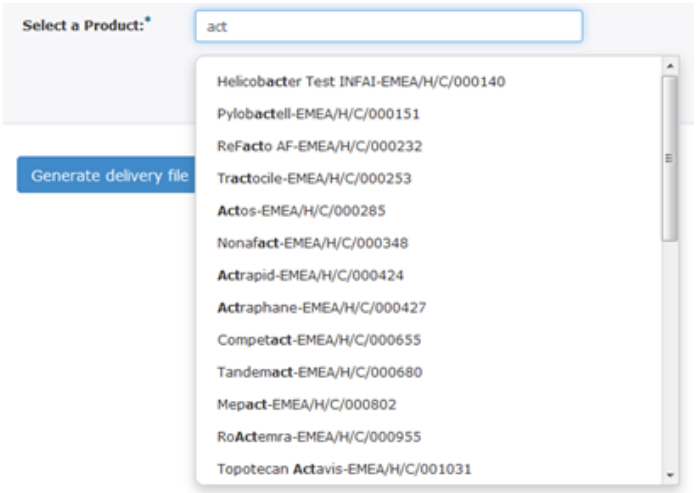
ASMF Manual field entry:



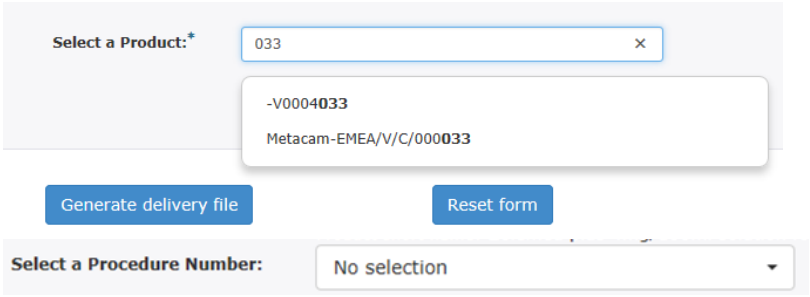
6	Search for the product by typing any part of the product name or EMEA product number in the 'Select product' field. The more you type the more the list is filtered. For veterinary ASMFs supporting an initial MA application,	Enter the name of the CAP for Single or 'lead' CAP for procedure that contains multiple CAPs or multiple CAPs and NAPs.

	start typing in the 'Select product' field any part of the product number e.g. 0001234. For Veterinary ASMF submissions the product name will not be displayed for products which have not been authorised yet.	**Please note** that for Veterinary ASMF submissions the product name and the substance name which is a part of the ASMF number will not be displayed for products which have not been authorised yet.

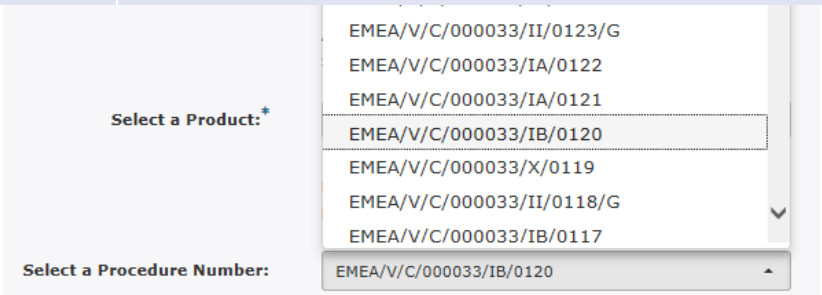
Human product selection:



Veterinary product selection for ASMF:



7	Select procedure number from predefined list.	



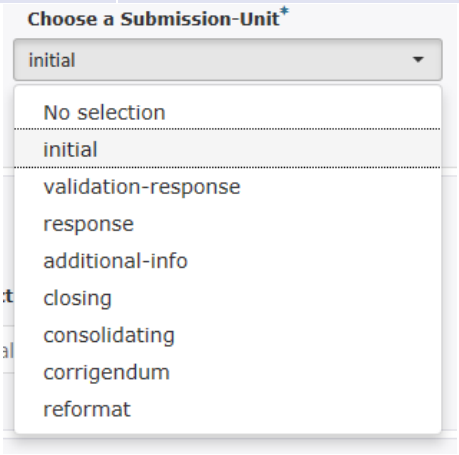
8	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

9. Create delivery file screen – PMF

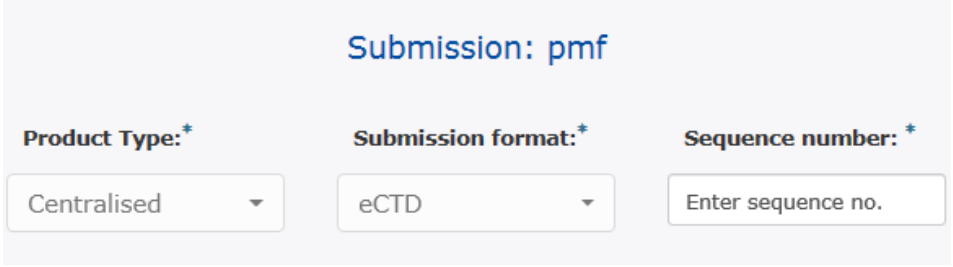
9.1. Create delivery file for PMF

Step	Description	Notes
1	Select Submission type 'PMF'. Submission mode is always single product.	

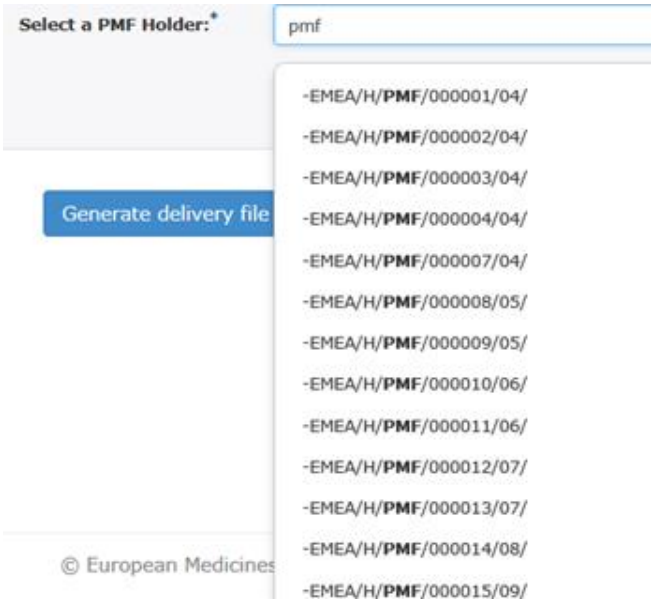
2	Select relevant Submission-Unit	



3	The Product type and the submission format cannot be changed and must always be 'Centralised' and 'eCTD'. Enter the submission eCTD sequence number.	The sequence number is always a numeric value (range from 0000 to 9999)



4	Select the PMF procedure by typing the PMF number. The more you type the more the list is filtered.	



5	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

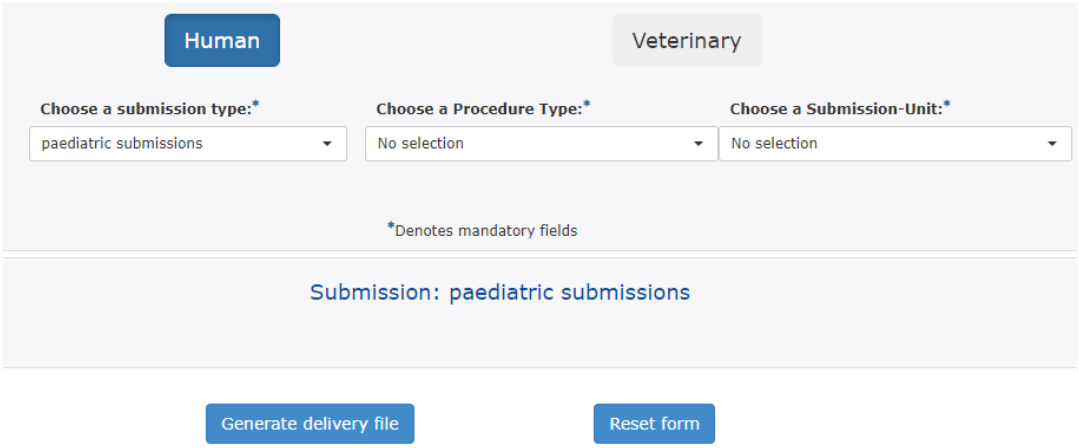
10. Create delivery file screen – Paediatric submissions

A major change has been introduced to the delivery files for paediatric submissions in v3.7.3.0 in October 2020 to provide more information to speed and simplify the processing of incoming paediatric submissions and to provide search attributes for the paediatric submissions which will be included in the Common Repository in near future.

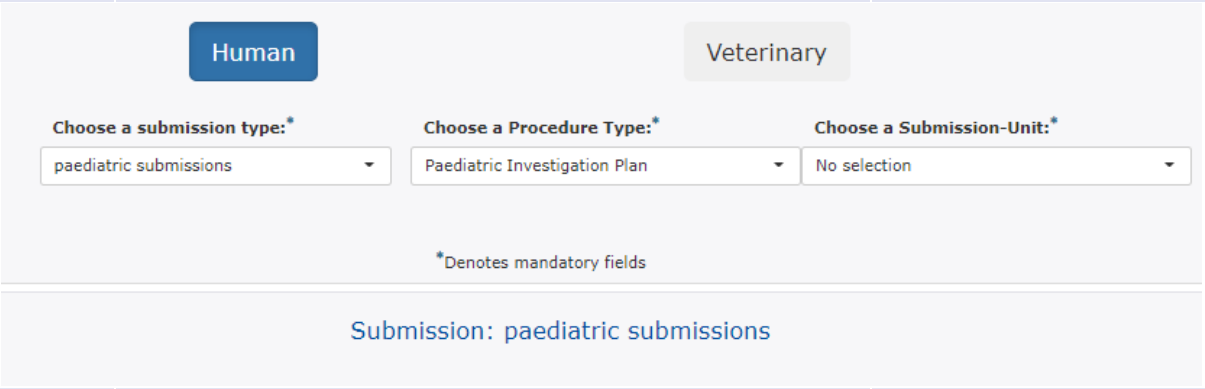
More information can be found from the Guidance on Paediatric submissions here.

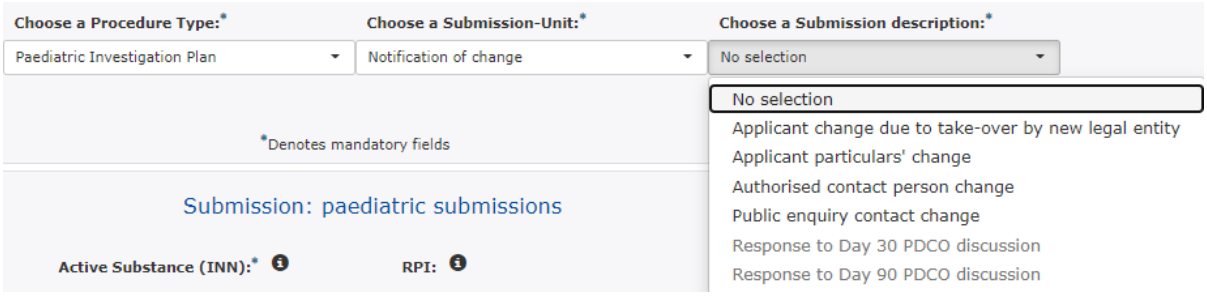
For any questions on technical issues, please contact EMA service desk.

For Paediatric submissions please contact ASK EMA.

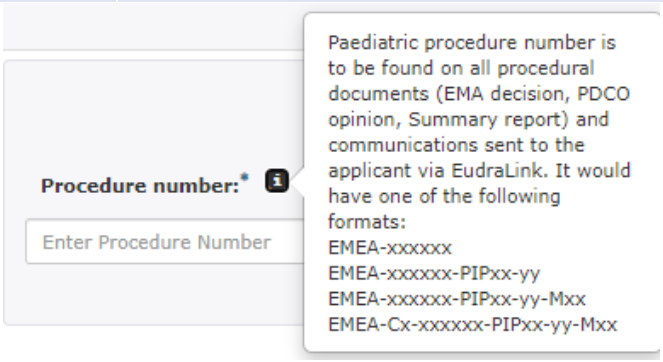


10.1. *Create delivery file for Paediatric submission*

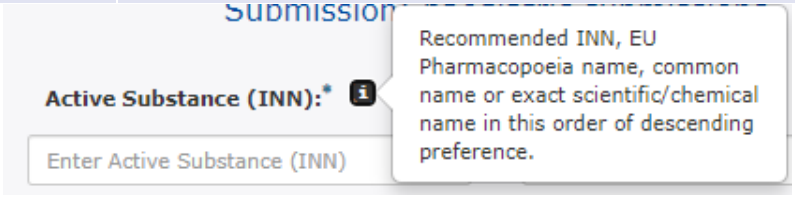
Step	Description	Notes
1	Select Submission type 'paediatric submissions' and proceed to select the relevant Procedure type and the relevant submission unit. Each submission should contain only a single 'regulatory activity' for example a submission should not contain both annual report and responses to PDCO request for information	Paediatric submissions covers all types of paediatric submissions e.g. Paediatric Investigation Plan (PIP) submissions, waivers, deferrals and modifications.
		
3	Depending on the selected Procedure type and the submission unit, you may need to select a Submission description.	



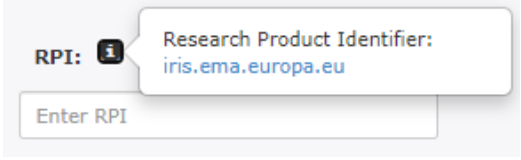
4	Enter the Procedure number. The procedure number is an alphanumeric value with a specific format. You can find this number from all procedural documents.	The PIP number field has been renamed to Procedure number and a format for the number is enforced



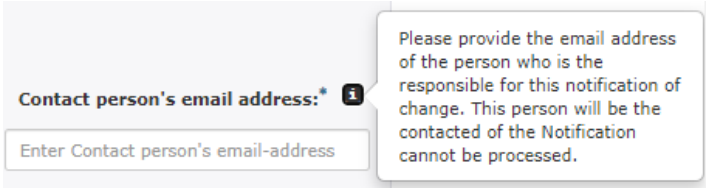
5	Enter the Active substance (INN). Alternatively, you can enter the pharmacopoeia name, common name or exact scientific/chemical name.	More information can be found from the Guidance on Paediatric submissions.



6	You are also invited to provide the RPI in this new optional field.	More information on the Research Product Identifier and how to obtain one can be found from the IRIS website.



7	For certain procedures you will be asked to provide the contact persons email address.	This contact person will be contacted in case the notification cannot be processed.



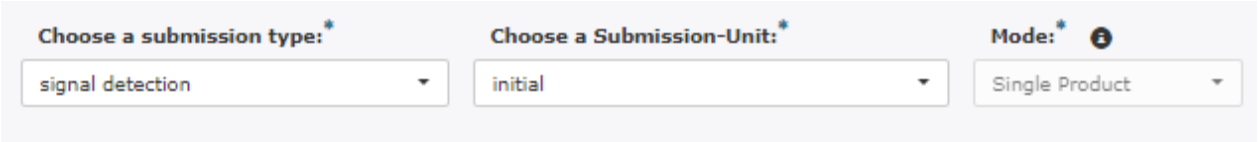
8	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

11. Create delivery file screen – Signal Detection (EPITT) submissions

Signal detection is performed by the EMA, Member States and MAHs. Member States, in collaboration with the EMA are responsible for EudraVigilance data monitoring for medicinal products authorised nationally (NAPs), including those approved via mutual recognition (MRP) and decentralised (DCP) procedures. For NAPs approved in more than one Member State, a worksharing has been organised whereby lead Member States have been appointed to monitor EudraVigilance data on behalf of the other Member States.
The responses should be submitted in English in eCTD format to the EMA within the timeline specified in the PRAC recommendation. The requested data should be submitted within the appropriate modules (e.g. 5.3.6. Reports of post-marketing experience) of the CTD.

11.1. *Create delivery file for Signal Detection (EPITT) submission for Nationally Authorised Product (NAP)*

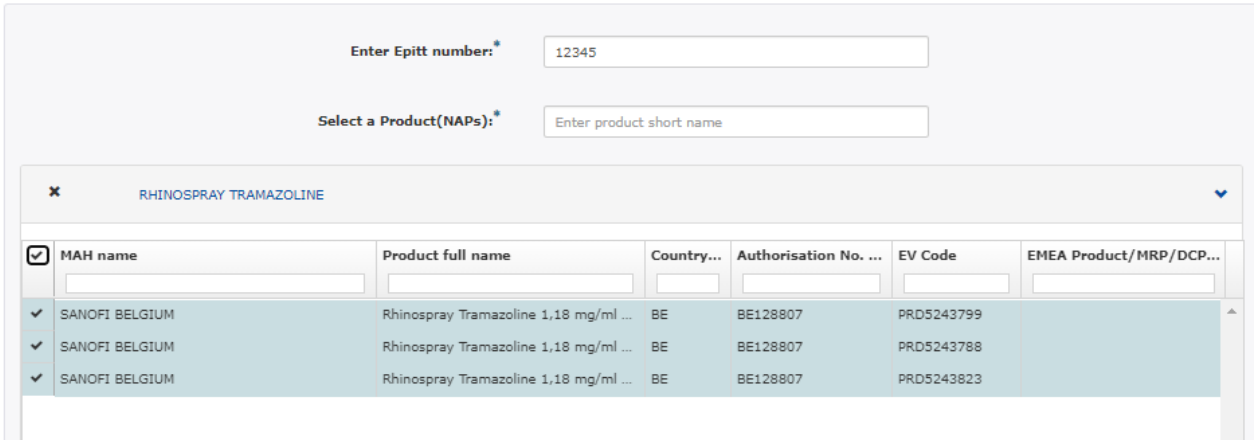
Step	Description	Notes
1	Select submission 'Signal Detection' and submission unit 'initial'. The mode is always single.	



2	The product type is defaulted to National. Please enter the eCTD sequence number.	The number should be the next number is the eCTD lifecycle of the product. There should be no standalone eCTD lifecycles created for signal detection submissions.

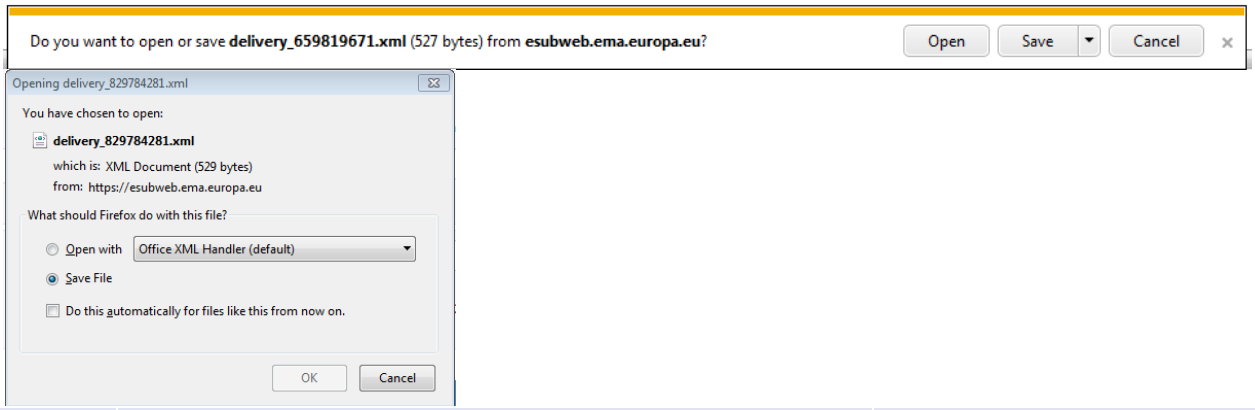
3	Enter the 5-digit EPITT number as provided in the request sent by EMA.	The number consists of 5 numbers
4	Search for the relevant product(s) by typing any part of the product name in the 'Select a product' field. The more you type the more the list filtered. The list of Nationally Authorised Products with retrieved from XEVDMP (Art. 57 database).	It is possible to select more than one product name from the list to ensure that all products and presentations are selected.
5	Expand the product details by clicking anywhere in the field with the selected product name and proceed to filter and select the relevant products/presentations. Multiple criteria may be used to filter the product selection.	

6	You can select all products/presentations by clicking to the field next to 'MAH name' field. Alternatively, click individual lines to select relevant products/presentations.	At least one of the products/presentation must be selected.
7	Close the selection by clicking anywhere in the field with the product name and repeat the previous step to include all products/presentations for which a single submission sequence has been prepared for.	

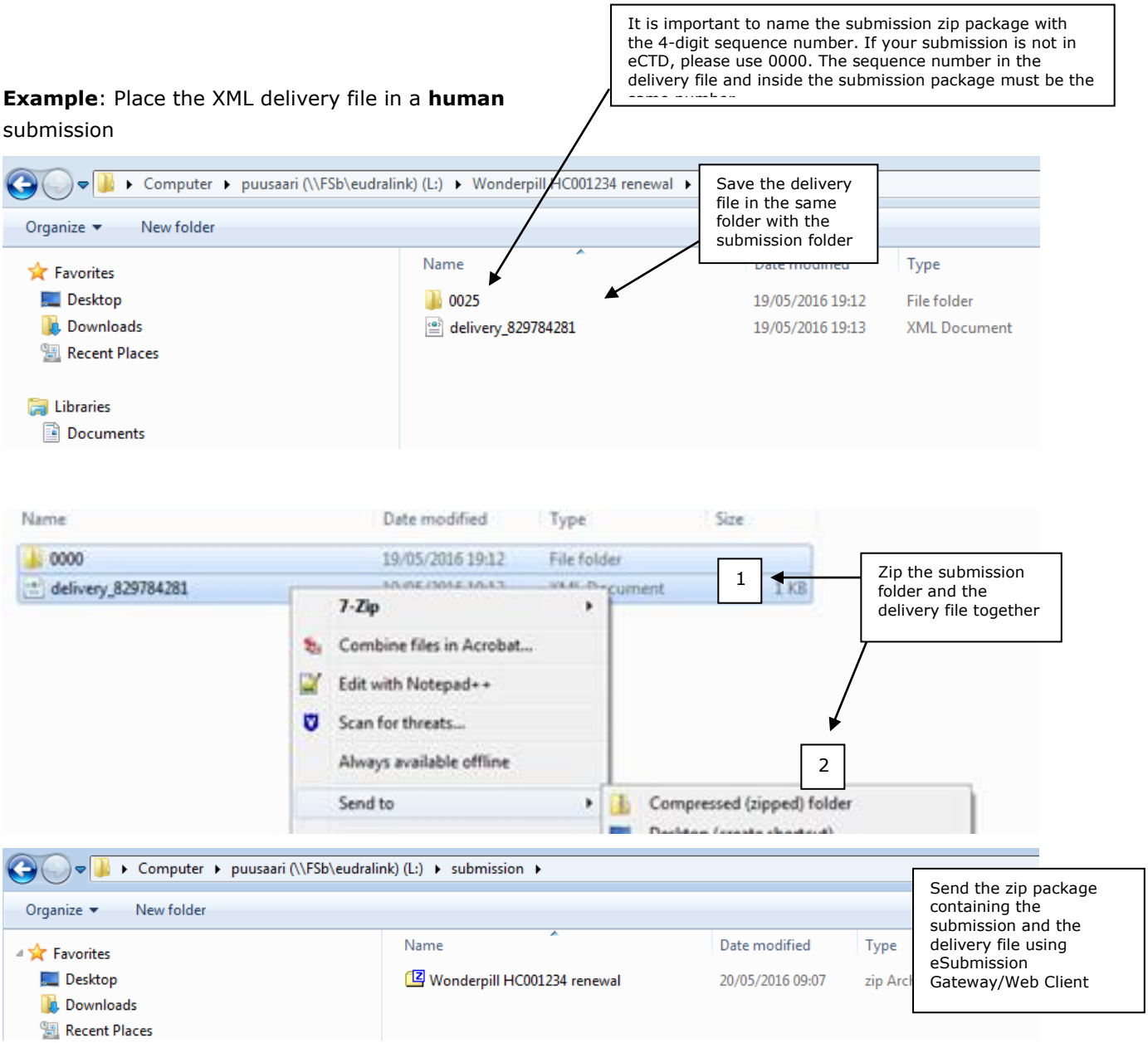


8	Click 'Generate delivery file' and save the delivery file on your computer.	The delivery file should not be amended or re-named.

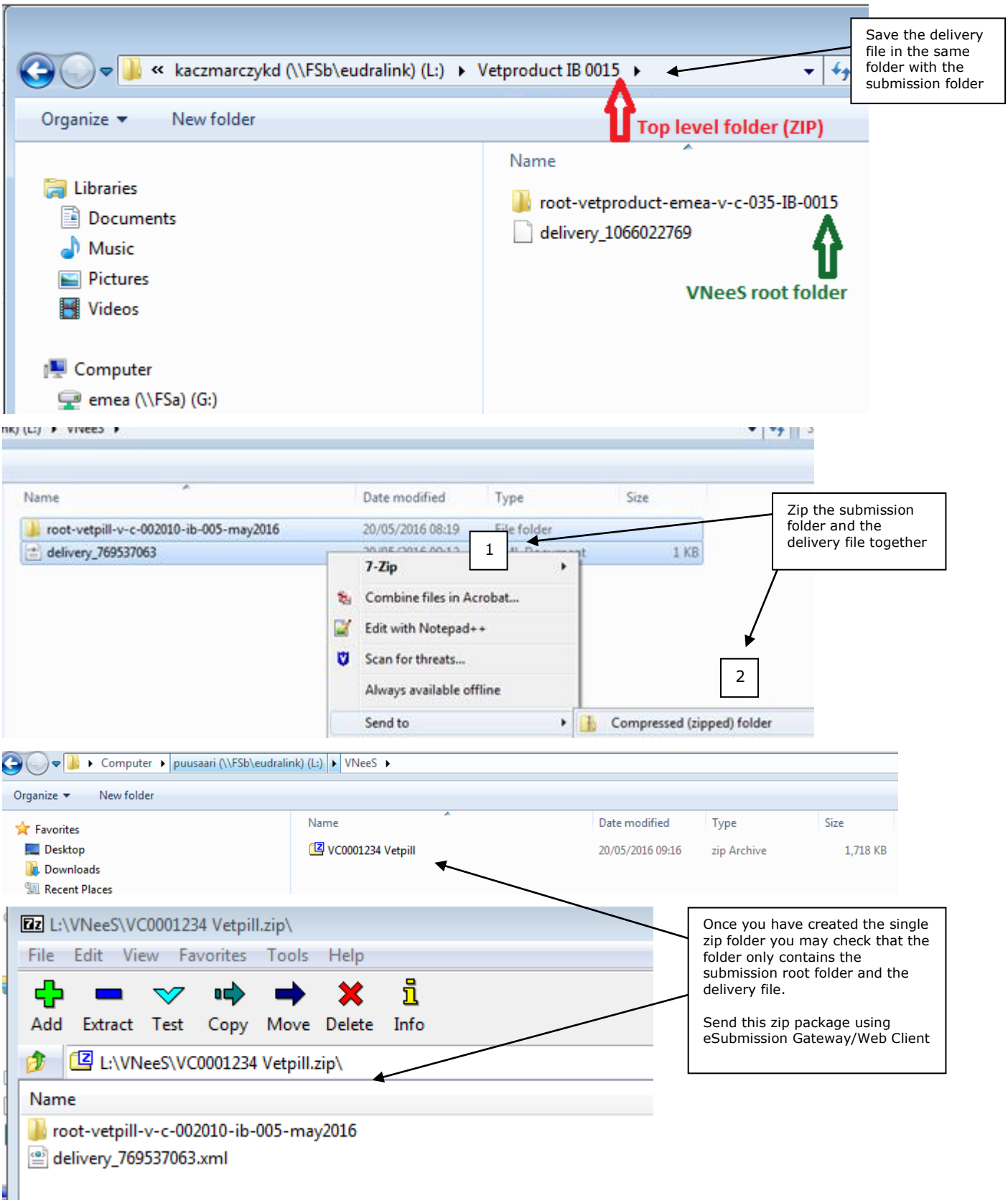
12. Saving the XML delivery file and preparing the submission package

Step	Description	Notes
1	When you have generated the delivery file it is possible to open the file to view it or to save it. The options how to open to view or save the delivery file vary depending which browser you are using	
		
2	Save the delivery file in a location where you can easily find and identify it (especially if you are creating multiple delivery files). It is a good practice to save the submission package in a clearly named folder. You can then easily save the xml delivery file in this same folder before zipping them together.	
3	The delivery file should be saved in the **top-level folder** of the submission package. For human and PIP submissions this means in the same level with the submission folder. For veterinary submissions in VNeeS, the XML delivery file should be located in a top-level folder on the same level as the VNeeS root folder (see example below).	Ensure your VNeeS root is placed in a higher-level folder together with the XML for easier zipping. Remember that the VNeeS checker should be run on the VNeeS root prior to zipping the root folder and the xml delivery file together.

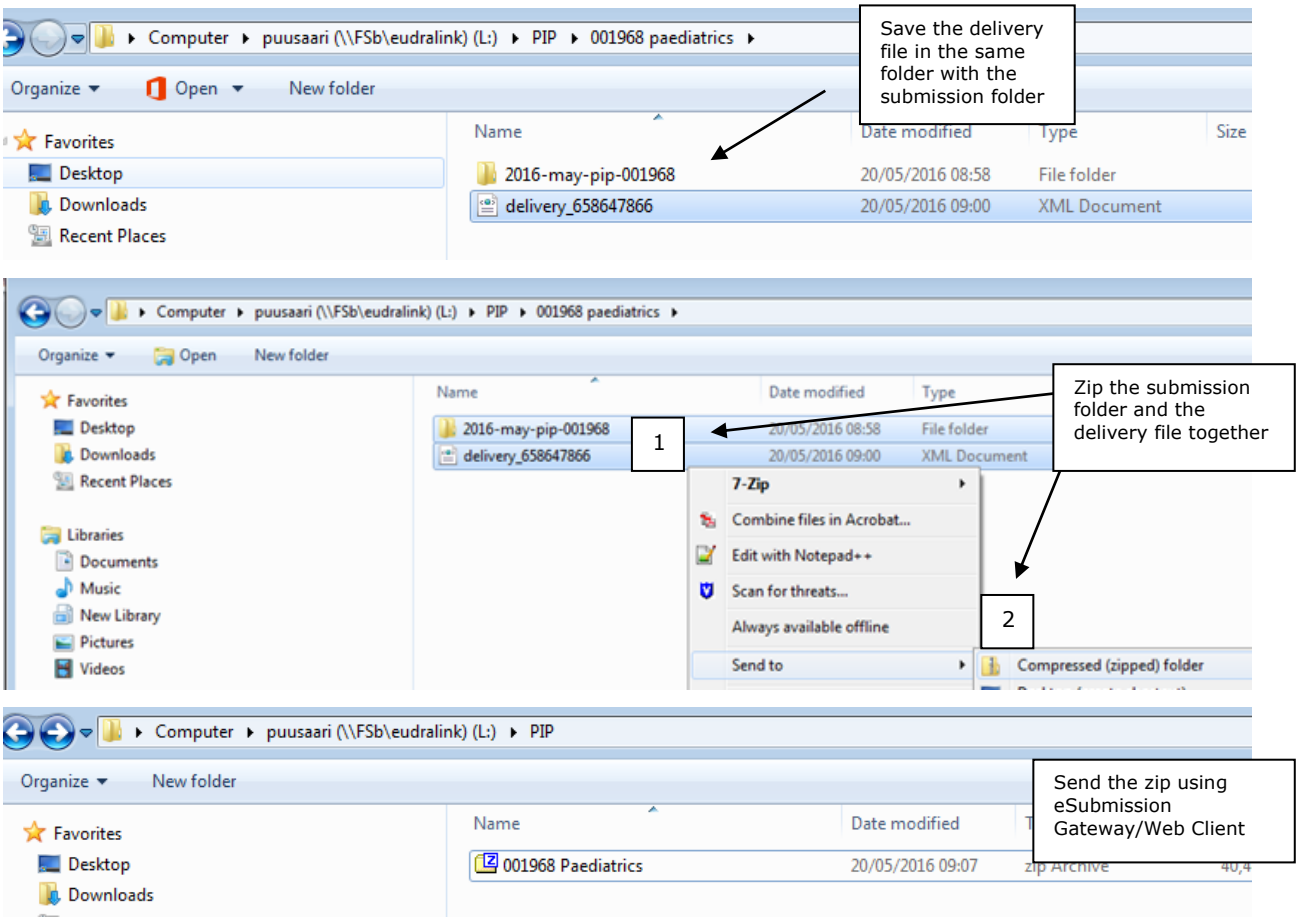
Example: Place the XML delivery file in a **human** submission



Example: Place the XML delivery file with the **Veterinary submission VNeeS** root folder into a high level (zipped) folder



Example: Place the XML delivery file in a **PIP** submission



Example: Place the XML delivery file in other **non-structured** submissions

If your submission is permitted to not follow any specific electronic format such as eCTD, NeeS or vNeeS, i.e. you are submitting a loose collection of documents or a single document and you have chosen 'Other' as Submission format, make sure your documents are first placed in a folder as in the above example for PIP submission. You can name this folder in whatever manner meaningful to you. Once this is done, place the delivery file on the same level as shown above and zip the submission folder and the delivery file together in the same manner.

4	It is very important to ensure that the delivery file is in the correct level within the submission zip folder. There must be no additional empty folders i.e. the folder structure must not be superfluous. Any deviations in the location of the delivery file will lead in to **failure of the submission**.	
5	Log into eSubmission Gateway or the eSubmission Web Client and send the package following instructions in the user guide.	See user guide '[How to send submissions via the Web Client]'


Axway Interchange
https://pgateway.ema.europa.eu/ui/
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
EMA Gateway : Production
User ID:
Password:
Log in

13. Issues with delivery file creation

After a new release you may experience issues due to cookies (clear the cache) to the old version. It is recommended to clear cookies and refresh the screen if any unusual behaviour is detected. For persistent issues: try 'InPrivate' or incognito browsing – open new instance Ctrl+shift+P in IE and Mozilla Firefox or Ctrl+shift+N in Google Chrome.

If you are experiencing issues with the XML delivery file screen or eSubmission Gateway/Web Client, please contact the EMA via the service desk portal.