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

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## **Document History**

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2.34	05/12/24	Updates to reflect changes from the amended variation regulation and the new Fee Regulation (NFR)	Kristiina Puusaari
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2.25	14/11/22	Updated to improve details on paediatric submissions	Kristiina Puusaari Andrea Davies
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Version	Date	Changes applied	Author
2.23	14/06/22	Updated version 4.0.0.0 to add 2 new submission types: Companion Diagnostics Consultation and Follow-up Companion Diagnostics.	Kristiina Puusaari
		Additionally, a technical update of the framework with an upgrade from AngularJS to Angular has been done. This technical update does not change any functionality; however, it provides new, different look and feel to the user interface. There are no changes to business rules/other features as a result of this update.	
		<b>NOTE:</b> Please note that the screenshots included in this guidance <b>have not been updated</b> to reflect the change related to update from AngularJS to Angular. This will be done gradually over time. This user guide reflects the previous look and feel of the system.	
2.22	27/01/22	Updated to reflect the Veterinary Medicines Regulation (EU) 2019/6.	Kristiina Puusaari
			Hannes Kulovits
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
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Version	Date	Changes applied	Author
2.14	04/11/19	Updated to reflect changes implemented in release v3.7.0.1	Kristiina Puusaari
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2.12	19/09/18	Updated to reflect changes implemented in release v3.6	Asim Qureshi
2.11	05/07/18	Updated to reflect changes introduced in $v3.5$	Sandeep Senguttuvan
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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
2.7	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
2.6	05/05/17	Update from release 3.2.0 RC4 to reflect changes to contact person contact details	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
2.4	20/02/17	Updated to include guidance how to fill in additional information for Referral submissions	Kristiina Puusaari
2.3	12/12/16	Updated to reflect the change from PIP submissions to Paediatric submissions	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

Version	Date	Changes applied	Author
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
2.0	25/07/16	Updated to reflect changes related to EU Module 1 specification v3.0.1	Kristiina Puusaari
1.1	31/05/16	Update – ancillary medicinal substances in medical device are out of scope during the pilot phase	Kristiina Puusaari
1.0	23/05/16	Original – documented usage of the delivery file creation functionality	Kristiina Puusaari

# 1. Introduction

This document serves as a simple guide for applicants to submit applications via the eSubmission Gateway / eSubmission Syncplicity 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 <u>eSubmission website</u>.

# 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

**Important note:** please ensure that you only include the xml delivery file, the sequence folder and if needed, the working documents folder in the submission zip folder. Nothing additional, e.g. the eCTD validation report or any other file **should not be included** in the submission zip folder. In general, the eCTD validation reports should not be sent to EMA, they are not required and cause additional work and if inserted in an incorrect location, may cause a failure of the submission.

The fields from the Formatted Table Template have been implemented 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.

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
Companion Diagnostic Consultation	New submission type to submit companion diagnostics to the EMA by a notified bodies
extension	Extension
lifting-suspension	Lifting of suspension
Follow-up Companion Diagnostic	New submission type to submit Follow-up companion diagnostics to the EMA by a notified bodies

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
Raw Data submission	New submission type to submit Raw Data pilot submissions to the EMA by applicants who wish to support their initial MAA application with Raw Data (to be used for submissions for agreed products only during the pilot period)
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 super-grouping (previously called IG))
var-type1ain	Type $IA_{IN}$ variation (single and super-grouping)

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-18	Procedures under Article 18 (Regulation 2022/123)
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.
<ul> <li>Paediatric Submission</li> <li>Available Procedure types;</li> <li>Annual Report</li> <li>Class-waiver confirmation request</li> <li>Compliance check</li> <li>Condition/indication confirmation request</li> <li>Discontinuation</li> <li>Modification of an agreed PIP</li> <li>Paediatric Investigation Plan</li> <li>Waiver</li> </ul>	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 subactivity 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

The list of Submission Types for Veterinary procedures has been updated to reflect the new procedure types as established in the VMP-Reg and number of previously available Submission Types have been removed from the list completely where there are no ongoing procedures for those Submission Types and there should be no new procedures started.

Number of procedure types which are no longer relevant under VMP-Reg remain available for the time being to ensure that applicants are able to submit subsequent submissions for ongoing procedures.

Submission Type	Description
exceptional circumstances re- examination	Procedure under Article 141(4) of Regulation (EU) 2019/6 establishes a possibility for applicant to request re-examination of opinions adopted by the CVMP
LM re-examination	Limited Market re-examination
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
pmss	Post-marketing safety studies (previously known as PASS)
rmp	Risk Management Plan (RMP)
transfer-ma	Transfer of a marketing authorisation
vra-e	Variation Requiring Assessment – extended timetable

vra-i	Variation Requiring Assessment - scopes under chapter I of Classification guidance
vra-r	Variation Requiring Assessment – reduced timetable
vra-s	Variation Requiring Assessment – standard timetable
referrals	
Article82	Referral under Article 82 of Regulation (EU) 2019/6
Article82 PhV	Referral under Article 82 of Regulation (EU) 2019/6
Article130(4)	Referral under Article 130(4) of Regulation (EU) 2019/6
Article141(1)	Referral under Article 141(1) of Regulation (EU) 2019/6
Article70(11)	Referral under Article 70(11) of Regulation (EU) 2019/6
Article58(4)	Referral under Article 58(4) of Regulation (EU) 2019/6
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)
vamf	Vaccine Antigen Master File (VAMF)
vamf-var	Variation on Vaccine Antigen Master File
vptmf	Vaccine Platform Technology Master File (VPTMF)
vptmf-var	Variation on Vaccine Platform Technology Master File

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 full list of possible submission unit values can be found in the below table. Please note that the submission unit types *closing*, *consolidating*, and *reformat* are only available for human submissions.

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)			
re-examination	New submission unit to be used for requesting a re-examination of an CHMP Opinion			
	* Use this unit for requesting re-examination of opinion for MAA, extension, Type II variation, renewal and annual re-assessment as well as Referral procedures.			
	Please note that regulatory guidance referring to how to send re-examination requests may be out of date. Re-examination requests should be submitted via the eSubmission (Syncplicity) Gateway using eCTD format where required for the procedure type.			
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'			
	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 s	ubmission description to be used for MRL submissions only
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#### PLEASE NOTE UPCOMING CHANGE FOR PAEDIATRIC SUBMISSIONS:

#### Paediatric submissions to launch on IRIS platform from 4 June 2024

Please note that from 4 June 2024, the following types of paediatric submissions must be carried out via <u>IRIS</u>:

- Initial paediatric investigation plan (PIP)
- Modification of an agreed PIP
- Product-specific waiver
- Compliance check
- Annual report on paediatric deferred measures
- Confirmation of applicability of a class waiver, or inclusion of an indication within a condition
- Discontinuation of paediatric development.

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 / eSubmission Syncplicity Web Client using xml delivery files is a 2-step task:

 Create a delivery file for your submission by navigating to <u>the eSubmission website XML</u> <u>delivery file preparation screen</u>. 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.

#### eSubmission eSubmission Home Introduction To facilitate the submission of regulatory information concerning marketing authorisations application for medicinal products to National Competent Authorities and EN Human eSubmission electronic submissions have been developed. eCTD v3.2 eCTD EU M1 specification or human medicinal products, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed an electr Veterinary eSubmission Document (eCTD). This standard is based on "M4: The Common Technical Document (CTD)" in its various parts. eSubmission expert group The current electronic version was developed by the eCTD Implementation Working Group and released as version 3.2 in February 2004. The European Union applie eSubmission expert group it with the European Module 1 documents Preparation of the next major version (version 4.0) is now ongoing within the ICH External Links For more information, please refer to the eCTD v.3.2, eCTD EU M1 specification and eCTD v.4.0 webpages Systems: **Common Repository** For veterinary medicinal products, a specific EU standard, Veterinary Non-eCTD electronic Submissions (VNeeS), that is based on the EU Notice to Applicants formal eAF For more information, please refer to the Veterinary eSubmission webpage eASMF ePMF The EU standards and related guidance documents are developed and maintained by the different key user groups and approved by the eSubmission expert group b **CESP Delivery** For technical support, visit the EMA Service Desk portal using your user credentials for a system hosted by EMA (except Eudravigilance). If you do not have an accou eSubmission Gateway & eSubmission Web Client For details on how to find us please click here Delivery file UI eSubmission Gateway 2 RSS news feed PAM submission form PLM Portal eAF (DADI) Previous news is available here **PLM Portal** What's New in eSubmission Today? 01-06-2023 PSUR Repository

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

**Note**: The filenaming conventions (instead of xml delivery files) 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 the submission package 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 and referral submissions.

# 4. Create delivery file screen – Centralised Procedure including Medical Devices and Companion Diagnostics

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.

For Human procedures, the required submission format is eCTD (mandatory for all centrally authorised, DCP, MRP and pationally authorised (NP) products). More information on the mandatory use of eCTD please see eSubmission website. Note: Applicants are reminded that eAFs should be edited and signed using Adobe Reader. Using Adobe Acrobat Pro may lead to rejection of the submission. More information can be found in the eAF website.	EUR s c i	OPEAN MEDICINES	AGENCY HEALTH
	Human		Veterinary
	Choose a submission type:*	Choose a Submission-Unit <sup>*</sup>	Mode: <sup>*</sup> 🚯
	Nothing selected	No selection	▼ Single Product ▼
		*Denotes mandatory fields	
	Generate	e delivery file	Reset form
Example: Human submissi	on types Ex	ample: Veterinary subr	nission types

#### CAP

annual-reassessment	
clin-data-pub-fv	
clin-data-pub-rp	
Companion Diagnostic Consultation	
extension	
Follow-up Companion Diagnostic	
lifting-suspension	CAP
maa	exceptional circumstances re-evamina
notification-61-3	I M re. evamination
pam-anx	Linite-examination
pam-capa	maa
pam-leg	pam-anx
pam-mea	pam-leg
pam-p46	pam-mea
pam-paes	pam-rec
pam-rec	pam-sda
pam-sda	pam-sob
pam-sob	pass
pass107n	rmp
pass107o	transfer-ma
pass107q	vra-e
Raw Data submission	vra-i
reformat/baseline	WED-F
reneval	vial
rmp	vid-s
transfer-ma	referrals
usr	MRL
var-typela	MRL-extension
var-type1ain	MRL-extrapolation
var-type1b	MPL full
var-type2	
withdrawal	MRL-modification
referrals	asmf
asmf	VAMF
pmf	vamf
PSUR	vann
atticle.50-WUO	vamt-var
andueroorwinto	VPTMF
psur/psusa	vptmf
paediatric submissions	vntmf-var
signal detection	vpun-vdi

# 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. <b>Veterinary submissions:</b> 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) 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:	Submission unit type describes the content at a
	Select the relevant 'Submission-Unit' for your submission. Requests for re-examination of CHMP Opinion should be submitted via the eSubmission Gateway using the submission unit 're-examination'.	lower level (a "sub-activity") which is submitted in relation to a defined regulatory activity.
3	Submission description	The submission description is
	For Centralised Procedure submissions, when submission- unit 'Response' is selected the attribute <b>submission</b> <b>description</b> 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.	automatically filled in for relevant post-authorisation procedures.
	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).	
4	For Human domain only:	The selection is defaulted to
	For Type 2 variations, Extensions and MAA submissions a radio button has been implemented to flag if the submission is 'Covid-19' related.	submission is Covid-19 related, please ensure that you tick 'Yes'.

		Human				Ve	eter	rinary		
	Choose	a submission type:*	Choose a Su	ıbmiss	ion-U	nit*		Mode:* 🚯		
	var-type	2	▼ initial			•		Single Product	t 🔻	
		C	ovid19 related: <sup>*</sup> • Y	es O	No					
	5	For Human domain Data/Real World For submission type • maa • extension • var-type2 • pam-paes • pass107n with submission un implemented to flat Data (RWD) to pre efficacy/effectivenee changes or to su requirement.	in only -fields re Evidence: es: it 'initial', a new ro g if the submission ovide evidence o ss of the medicine pport or satisfy	adio l n cont n the a po	butto tains e sa supp ost-a	on has bee Real Wor fety and/ ort labellir uthorisatio	en Id or ng on	If your ini contains F indicate 'y and select options fo	itial submissio RWD/RWE, ple yes' using the t relevant sub or further deta	n slider - ils.
Real	World Data So	Does the submis of the medicine, purces*	sion contain real world data* (RWD) to support labelling changes or to sup	co provide oport or sa Rea	evidence itisfy a po I World D	on the safety and/o st-authorisation req lata Purposes*	or effica juireme	acy/effectiveness	Example of RWD (not exhaust list): data issued from electron health/medical records (EHR), registry. claims databases, dig health technologies, patient questionnaires.	ive nic ital
	6	When selecting 'mandatory fields ap option from each ca RWD purposes.	yes' by moving pear where you m ategory to describe	the ust se the l	slid elect RWD	er, furth at least or source ar	er ne nd	If the opti selected t mandator appears to of the oth	ion 'other sour hen a further, y free text fiel o provide the ler sources.	rces' is d details
Real	World Data So	Does the submis of the medicine,	sion contain real world data* (RWD) to support labelling changes or to sup	o provide oport or sa Rea	evidence itisfy a po	on the safety and/o st-authorisation req lata Purposes*	or effica Juireme	acy/effectiveness	Example of RWD (not exhaust list): data issued from electron health/medical records (EHR), registry, claims databases, dig health technologies, patient questionnaires.	ive nic ital
	Electroni	ic health/medical records data				To provide inforr	matio	n on disease epide	emiology	
0	Medical	claims data		[		To provide inform	matio	n on standards of	care	
	Registry	data escription/dispension/utilisation da	ta (which may be collected	5		investigating the interest	e effic	acy/effectiveness	and/or safety of a med	icine of
	from pha claims)	armacies/-ists and are different fro	om administrative medical			To evaluate the f criteria	feasib	oility of the choice	of inclusion and exclus	ion
	Data fro	m digital health technologies in no	n-research settings	0		To inform on the	e recri	uitment of study p	opulation in a clinical s	tudy
	Other da	ita sources, eg. patients generate s, questionnaires, that can inform	d data/patients reported on health status			To identify relev: study	ant er	ndpoint(s) to be fu	urther studied in a clini	cal e
	Real World	Data Sources*				To inform on the	effec	ctiveness and/or s	afety of a medicine of i	nterest
	Other da	ta sources, eq. patients generated	data/patients report *			To measure the a medicine of int	presc terest	ription, dispensing t	g and/or utilisation patt	erns of
	RWD Oth	er Sources*				To measure the	effect	tiveness of risk mit	nimisation measures	

7	<ul> <li>For Human domain only – radio button related to SEND Data package - New:</li> <li>For submission type 'maa', for all submission units, a new radio button has been implemented to flag if the submission contains SEND Data package.</li> <li>IMPORTANT: The SEND package must be included in the working documents folder.</li> <li>IMPORTANT: The SEND package must be included in the working documents folder.</li> </ul>			maa submission s SEND package, ndicate 'yes' using the utton. ND data packages can included in the documents folder gether with the eCTD sion to provide dised format non- data to support MAA ions.			
Submission Ty	pe*	Submission-Unit*	-	Mode*	6		
maa	*	initial	*	Single	Product		
	SENI	Covid19 related:* Data package Included:*	<ul><li>Yes</li><li>No</li><li>Yes</li><li>No</li></ul>				
8	For Human domain	only:		If your v	variation is submitted		
	For all variations w mandatory radio but the submission is 'Nit	ith submission ur ton has been impl rosamine' related.	nit `initial', a new lemented to flag if	in order Art 5(3) nitrosan that you	in order to comply with the Art 5(3) recommendation on nitrosamines, please ensure that you tick 'Yes'.		
			Please confirm (Y/N) that	the			
Nitrosam	ine related procedure:* 0	⑧ Yes ○ No	variation is being submitte order comply with the recommendations of the a S(3) scientific opinion on nitrosamines (EMEA/H/A- S(3)/1490), i.e. step 3 of for review.	ed in irticle the call			
9	Human domain:						
	For Centralised Proce Product type and the changed and must al Submissions for Natio be included for exam possible to change the format to 'National' a	dure human subm submission format ways be 'Centralise onally Authorised P ple in a referral pro e product type and nd 'NeeS' or 'Othe	issions, the t cannot be ed' and `eCTD'. products that may ocedure it is d submission r' as applicable.	The sec always (range	e sequence number is ways a numeric value ange from 0000 to 9999).		
	Enter the submission eCTD format submiss the next sequential n If a failure Acknowled sequence number sh to the sequence num For initial MAA submi normally 0000. To allow for easy cro Users can optionally	eCTD or NeeS seq sions this number s umber in the produ dgement is received ould be used unles ber itself. ssions the sequence ss referencing of re enter a related seq	uence number. For should always be uct lifecycle. d, the same s the error relates ce number is elated submissions; uence number.	More information on the related sequences can be found from the <u>Harmonised</u> technical eCTD guidance.			
	Veterinary domain						
	In veterinary submiss set to "Centralised" a exception of worksha For Centralised Proce	sions, the Product f nd cannot be chan ring and referral su dure veterinary su	type is by default ged (apart the ubmissions). bmissions <i>,</i> the	If CTD i of part dossier, format	is used as the format II (Quality) of a VMP , the submission to select is "VNeeS".		
	Submission format ca options: • "VNeeS (pha	an be selected from	t) <version>",</version>	As format requirements evolve over time in line with the EU Telematics			

- "VNeeS (immunological product) <version>" or
- "VNeeS (Biological product) <version>"
- "Other".

For MAA submissions, option "Other" cannot be used.

For example, "VNeeS (pharmaceutical product v3.0)" means the structure follows the <u>Guideline on eSubmission</u> for Veterinary products - version 3.1, TABLE 1: Folder structure and Standard files for an electronic application for a pharmaceutical product. "VNeeS (immunological product v3.0)" means the structure follows the <u>Guideline</u> on <u>eSubmission for Veterinary products - version 3.1</u>, TABLE 3: Folder structure and Standard files for an electronic application for an immunological product.

10 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.

Medical Device Related Consultation: 🗹

For any subsequent submissions of medical devices, you can search the product by name or typing H/D.

For Companion Diagnostics Consultation and Follow-up Companion Diagnostic; select the submission type Companion Diagnostics Consultation. Start typing in the 'Select product' field the product name or any part of the product number for initial consultation. The system will automatically recognise these types of products and the submission format is automatically changed to 'Other'. It is not possible to change this manually.

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 eSubmissions Roadmap for use of VNeeS, applicants should always consult the <u>Veterinary eSubmissions</u> <u>Website</u> for current guidance on the mandatory or recommended format for their submission type.

If the submission relates to an ASMF in CTD format, select "Other".

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).

For non eCTD submissions, such as the Companion Diagnostics, you can enter 0000. 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:

- Companion Diagnostics Consultation
- Follow-up Companion Diagnostic
- 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 submission by using 'Add related procedure' field.

For variations Type IB and Type II and Follow-up Companion Diagnostic 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.

For pam-sda a new mandatory EPITT number field has been added. The EPITT number must be included for all submission units.

#### Human and Veterinary domains:

It is 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 only)
- Variations Type IA<sub>IN</sub> (H only)
- Variations Type IB (H only)
- Variations Type II (H only)
- VR-E (V only)
- VR-I (V only)
- VR-S (V only)
- VR-R (V only)
- 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).

Product names are not shown for veterinary submissions prior to the initial application for data protection.

Product numbers for veterinary CAPs in postsubmission 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.

The second se
For any post-authorisation activity; start typing in the
'Select product' field the product name or <b>any</b> part of the
product number.

### Example: Human Renewal initial

	renema		_		_	Single Product	Ť	
			*Der	otes mandatory fields				
			Submi	ssion: renewal				
Product Type* Centralised	Ŧ	Submission form eCTD	lat <sup>u</sup> 🗸	Sequence nur	nber*		Related sequ	ence
RMP included								
Select a product*								
enewal type 🔘 1 year co	nditional 🔘 5 year	r						
Purchase Order number*	0							
ample: Huma	n Type II y	variation i	nitial					
Si	ubmission Type*	Ť	Submission-Unit*	v	Mode*	Des dura	. <b>O</b>	
V	ar-typez		Initial		Single	Product		
			Covid19 related:*	🔵 Yes 💿 No				
	Does the	e submission contain r	real world data* (RWD) to	provide evidence on the safet	v and/or efficad	cv/effectiveness	•	
	Does the of the m	e submission contain r edicine, to support lal	real world data* (RWD) to belling changes or to sup	o provide evidence on the safet port or satisfy a post-authorisa	ty and/or effication requirement	cy/effectiveness nt?	0	
	of the m	e submission contain r redicine, to support lal	real world data* (RWD) to belling changes or to sup	o provide evidence on the safet port or satisfy a post-authorisa	ty and/or effication requirement	cy/effectiveness nt?	0	
	Does the m	e submission contain r vedicine, to support lal	real world data* (RWD) to belling changes or to sup;	o provide evidence on the safet port or satisfy a post-authorisa	y and/or efficad	cy/effectiveness nt?	0	
	Does the of the m	e submission contain r edicine, to support lal	real world data* (RWD) to belling changes or to sup *Denotes n	o provide evidence on the safet port or satisfy a post-authorisa nandatory fields	y and/or efficad	cy/effectiveness	0	
	Does the of the m	e submission contain r edicine, to support lai	real world data* (RWD) to belling changes or to sup *Denotes n	o provide evidence on the safet port or satisfy a post-authorisa nandatory fields	ty and/or effication requirement	cy/effectiveness	0	
	Does the of the m	e submission contain r ledicine, to support lai	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields <b>n: var-type2</b>	ty and/or efficat	cy/effectiveness	6	
Product Type"	Does the of the m	e submission contain r edicine, to support lai	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields <b>n: var-type2</b> Sequence number*	ry and/or efficad	cy/effectiveness	elated sequence	
Product Type* Centralised	Does the of the m	e submission contain r edicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	o provide evidence on the safet port or satisfy a post-authorisa nandatory fields <b>n: var-type2</b> Sequence number*	y and/or efficad	cy/effectiveness nt?	elated sequence	
Product "spor" Centralised	Does the of the m	e submission contain r ledicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	porvide evidence on the safet port or satisfy a post-authorisa nandatory fields <b>n: var-type2</b> Sequence number* Brexit Procedure:*	y and/or efficad tion requirement Yes O No	cy/effectiveness	elated sequence	
Product Type* Centralised	Does the of the m	e submission contain r ledicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields <b>n: var-type2</b> Sequence number* Brexit Procedure:*	y and/or efficad tion requirement Yes () No	cy/effectiveness	elated sequence	
Product "yes" Centralised RMP included	Does the of the m	e submission contain r edicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	o provide evidence on the safet port or satisfy a post-authorisa nandatory fields <b>n: var-type2</b> Sequence number* Brexit Procedures*	y and/or efficad tion requirement Yes No	cy/effectiveness nt?	elated sequence	
Product "yea" Centralised RMP included Select a product Aprovel - EMEA/H/C/000141 Product EMA number:	Does the of the m	e submission contain r edicine, to support lai Submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	port or satisfy a post-authorisa nandatory fields <b>n: var-type2</b> Sequence number* Brexit Procedure:*	y and/or efficad tion requirement Yes O No	cy/effectiveness nt?	elated sequence	
Product Type* Centralised RMP included Select a smoott* Aprovel - EMEA/H/C/000141 Product EMA number: Product EMA number:	Does the of the m	e submission contain r ledicine, to support lai Submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requirement Yes O No	cy/effectiveness nt?	elated sequence	
Product Twee* Centralised RMP included Select a conduct* Aprovel - EMEA/H/C/000143 Product EMA number: Product short name: ATC Code:	Does the of the m     EMEA/H/C/0001     Aprovel C09CA04	e submission contain r ledicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup "Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requiremen Yes O No	cy/effectiveness	elated sequence	
Product Type* Centralised RMP included Select a servicet* Aprovel - EMEA/H/C/000143 Product EMA number: Product short name: ATC Code: INN:	Does the of the m I EMEA/H/C/0001 Aprovel C09CA04 Irbesartan	e submission contain r ledicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requiremen Yes () No	cy/effectiveness	elated sequence	
Product Type* Centralised RMP included Select a system Aprovel - EMEA/H/C/000143 Product EMA number: Product short name: ATC Code: INN: MAH:	Does the of the m I EMEA/H/C/0001 Aprovel C09CA04 Irbesartan sanofi-aventis n	e submission contain r ledicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requirement (ves O No	cy/effectiveness ht?	elated sequence	
Product Type* Centralised RMP included Select a product* Aprovel - EMEA/H/C/000141 Product EMA number: Product short name: ATC Code: INN: MAH:	Does the of the m	e submission contain r ledicine, to support lai submission format* eCTD	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requirement Yes () No	cy/effectiveness nt?	elated sequence	
Product "rees" Centralised RMP included Select a product" Aprovel - EMEA/H/C/000141 Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure		e submission contain r ledicine, to support lai submission format* eCTD 41	real world data* (RWD) to belling changes or to sup "Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requiremen Yes 🔵 No	cy/effectiveness nt?	elated sequence	
Product "yest Centralised RMP included Select a product" Aprovel - EMEA/H/C/000143 Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedur Please provide the name(s) are being	Does the of the m  Methods of	e submission contain r edicine, to support lai Submission format* eCTD 41 41 roupe to <b>1</b>	real world data* (RWD) to belling changes or to sup "Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requiremen Yes 🚫 No	cy/effectiveness nt?	elated sequence	
Product Type* Centralised RMP included Striet a product Aprovel - EMEA/H/C/000141 Product EMA number: Product Short name: ATC Code: INN: MAH: Nitrosamine related procedur Please provide the name(s same change(s) are being Enter product name(s)	Does the of the m of the m EMEA/H/C/0001 Aprovel C09CA04 Irbesartan sanofi-aventis g re:* O Yes N s) of any centrally av applied for outside	e submission contain r ledicine, to support lai submission format* eCTD 41 41 41 41 41 41	real world data* (RWD) to belling changes or to sup *Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:*	y and/or efficad tion requirement	cy/effectiveness ht?	lelated sequence	
Product "yes" Centralised RMP included RMP included Product EMA number: Product BMA number: Product Short name: ATC Code: INN: MAH: Nitrosamine related procedur Please provide the name(s same change(s) are being Enter product name(s)	Does the of the m of the m EMEA/H/C/0001 Aprovel C09CA04 Irbesartan sanofi-aventis g re:* O Yes O N s) of any centrally at applied for outside	e submission contain r edicine, to support lai submission format* eCTD 41 41 41 41 41 41 41	real world data* (RWD) to belling changes or to sup "Denotes n Submissio	p provide evidence on the safet port or satisfy a post-authorisa nandatory fields Sequence number* Brexit Procedure:* () 1	y and/or efficad tion requirement	cy/effectiveness nt?	elated sequence	

Choose a submission type:*	Choose a Submis	sion-Unit <sup>*</sup>	Choose a Submission descrip	otion* Mode:* 🚯
var-type1b	✓ response	•	Responses to RSI	✓ Single Product ✓
	*	Denotes mandatory fields		
	Su	ıbmission: var-type	1b	
	Product Type:*	Submission format:*	Sequence number: *	Related sequence:
	Centralised -	ectd 🔹	0015	Enter related sequence
	RMP included:			
	Select a Product:*	sa		
		Abasaglar-EMEA/H/C/00 Reasanz-EMEA/H/C/002 BESPONSA-EMEA/H/C/00 Veltassa-EMEA/H/C/004	2835 817 04119 180	
	Generate delivery file	Insulin lispro Sanofi-EMI Lacosamide Accord-EME	EA/H/C/004303 A/H/C/004443	
		Sancuso-EMEA/H/C/002 Ibandronic acid Sandoz-	296 EMEA/H/C/002367	
	© European Medici	<sup>n</sup> Clopidogrel/Acetyl <b>sa</b> licyl	ic acid Zentiva-EMEA/H/C/001144	4

#### Example: Human Type IB variation responses



If the chosen product is part of the first set of regulatory procedures onboarded in the new platform, the dropdown menu will display additionally the new procedure numbers (examples below)

Identifier	Procedure
EMA/ <b>VR</b> /xxxxxxxxxx	Human variations Type II, IB, IA(IN)
MA/ <b>N</b> /xxxxxxxxxx	Art. 61(3)
EMA/ <b>T</b> /xxxxxxxxxx	Marketing Authorisation Transfer (Human and Vet)
EMA/ <b>S</b> /xxxxxxxxx	Annual re-assessment
EMA/ <b>R</b> /xxxxxxxxx	Renewal
EMA/ <b>X</b> /xxxxxxxxxx	Extension

**Example:** Human Type IB variation responses when initial processed in the new platform **New** 

				Submis	51011. V	ur cyperb
	Product Type* Centralised	,	Submission format* eCTD	~		Sequence number
	RMP included					
	Select a product* Duloxetine Zentiva - EMEA/H,	/C/003935			8	
	Product EMA number:	EMEA/H/C/00393	5			
	Product short name:	Duloxetine Zentiv	a			
	ATC Code:	N06AX21				
	INN:	Duloxetine hydro	chloride			
	MAH:	Zentiva k.s.				
	No selection			Í		
Π	EMA/VR/0000166577					
	EMEA/H/C/003935/IB/0015/0	3				

#### 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.

A

-	var-type1a		initial		Single Product	
			*Deno	tes mandatory fields		
			Submiss	ion: var-type1a		
Product Type* Centralised	¥	Submission format* eCTD	Ŧ	Sequence number* 0025		Related sequence
RMP included				Brexit Procedure:* O Ye	s 🔿 No	
version Number* 2						
Select a product* Mosquirix - EMEA/H/W/00	02300			0		
Product EMA number:	EMEA/H/W/00	12300				
Product short name:	Mosquirix					
ATC Code:	J07XA01					
INN:	RTS,S [portio	n of P. Falciparum circumsp	oorozoite protein f	used with hepatitis b surface antigen	(RTS), and combined wit	h hepatitis B surface antigen (S)]
MAH:	GlaxoSmithkli	ine Biologicals SA				
Nitrosamine related proced	ure:* 🔿 Yes 🧿	No O				

## Submission: var-type1b

	Human		vecenner,					
Submission Type* Companion Diagnostic Consultation	Submission-Unit* response	▼ Submissi	ion description*	Node' Single Product	0			
	Covid19 related	l:* 🔿 Yes 💿 No	, ,					
	Contains Request for change of Applicant	tı* ○ Yes ○ No	5					
	*Denotes	s mandatory fields						
S	ubmission: Companie	on Diagnostic	Consultation					
oduct Type" antralised	Submission format*	Sequence number* 0000		Related sequence				
RMP included					-			
Select a product*		•						
Product EMA number: EMEA/H/D/00002	02	ů						
Product short name: Steen Solution								
INN: HUMAN ALBUMI	N SOLUTION							
MAH: XVIVO Perfusion	AB							
	Generate delivery file	Reset form						
males Follow up	Componion Di	agnostic	initial					
Submissi		agnostic	Submission-Unit*		Mo	de*	, e	
Follow-	up Companion Diagnostic		initial		Sir	ngle Product		
			Covid19 related:*	🔵 Yes 🔘 No				
	Sub	omission:	*Denotes ma	ndatory fields Companion	n Diagno	stic		
Product Type* Centralised	Sub Submiss Other	omission:	*Denotes ma Follow-up	ndatory fields Companion Secuence number* 0013	n Diagno	stic	Related seque	ence
Product Type* Centralised	Sub submiss Other	omission:	*Denotes ma <b>Follow-up</b>	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	n Diagno	stic	Related seque	ence
Product Type* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/0	Submiss Other	omission:	*Denotes ma Follow-up	ndatory fields <b>Companion</b> Secuence number* 0013 Brexit Procedure:*	n Diagno ○ Yes ○ 1	stic ∾	Related seque	ence
Product Type* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number:	O0002	omission:	*Denotes ma Follow-up	Decourse of the second of the	n Diagno ○ Yes ○ 1	stic ∞	Related seque	ence
Product Twos* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name:	Sub Submiss Other 00002 EMEA/H/D/000002 Steen Solution	omission: sion format*	*Denotes ma <b>Follow-up</b>	ndatory fields <b>Companion</b> Secuence number* 0013 Brexit Procedure:*	∩ Diagno ⊖ ves ⊖ 1	stic ∾	Related seque	ence
Product Type* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code:	00002 EMEA/H/D/00002 Steen Solution	omission:	*Denotes ma Follow-up	Decuence number* 0013 Brexit Procedure:*	n Diagno	stic <sup>No</sup>	Related seque	ence
Product Twee* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN:	Sub Submin Other 00002 EMEA/H/D/000002 Steen Solution HUMAN ALBUMIN SOL	omission: sion format*	*Denotes ma	ndatory fields <b>Companion</b> Secuence number* 0013 Brexit Procedure:*	O Ves ○ 1	stic	Related seque	ence
Product Type* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN: MAH:	000002 EMEA/H/D/000002 Steen Solution HUMAN ALBUMIN SOL XVIVO Perfusion AB	omission: lien format*	*Denotes ma Follow-up	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	• Diagno	stic <sup>No</sup>	Related seque	ence
Product Twee* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure	Sub Submit Other 00002 EMEA/H/D/000002 Steen Solution HUMAN ALBUMIN SOL XVIVO Perfusion AB * O Yes O No C	Dission:	*Denotes ma	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	O Ves ○ 1	stic	Related seque	ence
Product Type* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure	000002 EMEA/H/D/000002 Steen Solution HUMAN ALBUMIN SOL XVIVO Perfusion AB * O Yes O No O	UTION	*Denotes ma	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	• Diagno	stic	Related seque	ence
Product Type* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure Please provide the name(s)	Sub Sub- Sub- Sub- Sub- Sub- Other Other Other Sub- Sub- Sub- Sub- Sub- Sub- Sub- Sub	UTION	*Denotes ma	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	O Ves O 1	stic	Related seque	ence
Product Twee* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure Please provide the name(s) Enter product name(s)	000002 EMEA/H/D/000002 Steen Solution HUMAN ALBUMIN SOL XVIVO Perfusion AB * O Yes No O	UTION	*Denotes ma	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	• Diagno	stic No	Related seque	ence
Product Trope* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure Please provide the name(s) Enter product name(s)	Sub Submission Other Other Content Other Content Conte	UTION	*Denotes ma	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	n Diagno	stic	Related seque	ence
Product TVDE* Centralised RMP included Select a product* Steen Solution - EMEA/H/D/O Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure Please provide the name(s) Enter product name(s)	000002 EMEA/H/D/000002 Steen Solution HUMAN ALBUMIN SOL XVIVO Perfusion AB * O Yes No O of any centrally authori ng applied for outside of ng applied for outside of	UTION	*Denotes ma	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	n Diagno	stic	Related seque	
Product Topo* Centralised  RMP included  RMP included  RMP included  Product EMA number: Product short name: ATC Code: INN: MAH: Nitrosamine related procedure  Please provide the name(s) Enter product name(s) Center product name(s) Center product name(s) Center of the same change(s) are besi Center product name(s) Center product name(s) Center product name(s) Center of the same change(s) are besi Center product name(s) Center produ	Sub Sub Submits Other Other MEA/H/D/000002 Steen Solution HUMAN ALBUMIN SOL XVIVO Perfusion AB * O Yes O No O of any centrally authori of any centrally authori me scope)	UTION	*Denotes ma	ndatory fields Companion Secuence number* 0013 Brexit Procedure:*	n Diagno	stic	Related seque	ence

### **Example:** Companion Diagnostics Consultation – response

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** <u>EMA's ServiceNow</u> 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.

Choose a submission type:*	Choose a Submission-Unit:*		Choose a Submis	sion description:*	Mode:* 🚯
var-typela 👻	response	-	Responses to RSI	-	Single Product 🔹
	*D4	enotes mar	idatory fields		
	Sub	omissio	n: var-type1a		
	Product Type:*	Submissi	on format:*	Sequence number:*	Related sequence:
	Centralised 👻	eCTD	•	0025	0025
	RMP included:	No No			
	Select a Product:*	Temodal-I	EMEA/H/C/000229	×	
	P P A I N	Product EM/ Product sho ATC Code: I INN: TEMO MAH: Merc	A number: EMEA/H/ rt name: Temodal L01AX03 ZOLOMIDE k Sharp & Dohme I	/C/000229 B.V.	
	Select a Procedure Number:	EMEA/H	/C/000229/IA/00	76/G 🔺	
		Grouping	(more than on	e scope): 🛛	

If the chosen product is part of the first set of regulatory procedures onboarded to the new platform, the dropdown menu will display the new procedure number EMA/**VR**/xxxxxxxxx. The new procedure numbering will no longer indicate the procedure type/mode as previously.

#### 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.

Choose a submission ty	pe:*	Choose a Submissi	ion-Unit <sup>*</sup>	Mode:* 🕕
extension	•	consolidating	•	Single Product 🔹
Includes	Yes		Choose a Withdray	wal type* 🜖
withdrawai.			No selection	-
		*Denotes mandato	No selection	
			procedure	
		Submission:	partial	

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

Includes withdrawal:	Yes		Choose a	e <b>Withdrawal t</b>	ype <sup>*</sup> 🕄	•
Example: Veter Choose a submis	inary Initial MAA sion type: <sup>*</sup> Ch	oose a Submiss	ion-Unit:*	Мос	de: <b>* A</b>	
maa	✓ Init	tial		▼ Sing	gle Product	•
	*	Denotes mandato	ory fields			
		Submissio	n: maa			
	Product Type: <sup>*</sup>		Submission for	mat:*		
	Centralised	•	VNeeS (Pharmac	ceutical product) v	3.0	•
	Select a Product:*	00				
		V <b>00</b> 5596				•
	Customer number:* 🟮	V <b>00</b> 5906				
	00006	V <b>00</b> 5944				
		V <b>00</b> 5992				
		V <b>00</b> 2001				
	Generate delivery file	V <b>00</b> 2010				

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

Choose a submission type:*	Choose a Submission-Unit*	Choose a Submission description <sup>*</sup>	Mode:*
maa 🔹	response 🔹	No selection 🔹	Single Product 🔹
	Covid19 related: <sup>*</sup> • Yes • No	o Applicant: <sup>*</sup> © Yes © No	

In case the submission unit is 'response' 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 <u>ServiceNow</u> or **leave the field empty**. <u>Employee Topic - Employee Center (europa.eu)</u>

If the chosen veterinary product is part of the first set of regulatory procedures onboarded to the new platform, the dropdown menu will display the procedure number as EMA/**VRA**/xxxxxxxxx.

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/super-grouping submissions. In case of WS/super-grouping submission, the WS/super-grouping (prevously known as) IG number should be selected from the list provided.

11	Select the pr reflected	oduct and check that the correct product is		
Example:	Human doma	in		
Select a	Product:	Zavicefta-EMEA/H/C/004027	×	
		Product EMA number: EMEA/H/C/004027 Product short name: Zavicefta ATC Code: J01DD52 INN: AVIBACTAM SODIUM,CEFTAZIDIME PENTAHY MAH: Pfizer Ireland Pharmaceuticals	'DRATE	

#### Example: Veterinary Initial MAA

Select a Product:	V002781	×
	Product EMA number: V002781	

Example:	xample: Pam-sda						
		Submission Type* pam-sda	•	Submission-Unit* initial	•	Mode* Single Product	. <b>O</b>
				*Denot	tes mandatory fields		
				Submis	sion: pam-sda		
Product Type Centralise	* d	-	Submission format* eCTD	-	Sequence number* 0045		Related sequence 0043
RMP inclu	ded						
Pam Code*				•	•		
CAT CHMP 60 L	ays PAM (H)				•		
Enter Epitt number* 29751							
		_					
Select a pr	oduct*						
12	Click ` your c	Generate del computer.	ivery file' and	d save th	e delivery file on	The deliver be amende	y file should not d or re-named.



13 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 super-grouping (previously IG) variation submission (human only)

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: super-grouping (Grouping of variations for CP previously known as IG)	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
	The Agency will allocate a 'high-level' cross-products 'IG' super-grouping procedure number, which will be used for the handling of procedures which affect more than one	ServiceNow.
	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	Note that super-grouping variations are those that affect more than one MA.
	contain "xxxx" as a placeholder for the product number. Examples: EMEA/H/C/xxxx/IG/002, EMA/VR/xxxxxxxxx (new platform)	If your variation is a grouping of several type IA changes but affects a single product do not
	<b>Note:</b> For grouping of several different changes affecting the <b>same</b> 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.	single product, do not select the super-grouping option. Leave the 'Mode' as <b>Single</b> (as this is referring to a single product). Please note that in the eCTD envelope mode value 'Grouping' should be selected for 'Grouped variations'.
	<b>Please note</b> that requesting this <b>high-level number</b> in advance is <b>mandatory</b> since this number must be included in the xml delivery file.	
	<b>NOTE:</b> The high-level procedure name is changed in the xml delivery file UI from IG to super-grouping prior to the entering into force of the new variation regulation. For IG variations that have been previously submitted with mode 'IG', please select option 'super-grouping'.	More information on <u>Grouping of variations</u> ' can be found from the Regulatory Post-Authorisation Guide (choose either 'human' or veterinary' tabs).

Submission Typ var-type1a	e* Submission-Unit*  initial	Mode* Super-grouping
		Single Product
		Super-grouping 🗸
	*Donotos mondatoru fielde	
	Human         Veterinary	
Submission Type* var-type1a	Submission-Unit* Submission description* response Responses to RSI	▼ Mode* Super-grouping ▼
2	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	sequence number is ays a numeric value nge from 0000 to 9999).

## Example: super-grouping submission

	Submission: var-type1ain						
Product Type:*		Submission format:*	Sequence number: *		Related sequence:		
Centralis	sed 👻	eCTD 🔹	0020		Enter related sequence		
3	Search for the product name of field. The more The product AT shown for visua Vet maa applica	relevant product by typi or product number in the you type the more the C code, INN and the MA al confirmation (these ar ations due to confidentia	ng any part of the e 'Select product' list filtered. H name are also re not shown for ality).	From 28 result o veterina the eSu no longe	B January 2022 as a f the VMP-Reg ary IG submissions via bmission Gateway are er possible.		
Example: super-grouping submission Select a Product:* FOSAVANCE-EMEA/H/C/000619							
		Product EMA number: EMI Product short name: FOS ATC Code: M05BB03 INN: ALENDRONIC ACID, MAH: Merck Sharp & Doh	EA/H/C/000619 AVANCE Vitamin D Ime Limited				
	Grouping (	more than one scope)	: 🕅				
4 Sele gro	ect the super-gro uping <b>variations</b>	uping number from the are those that <b>affect n</b>	list. Please note tha nore than one proc	t super- <b>luct</b> .	In case the super-grouping number (previously		

	The system displays those product i.e. it is not possifi doesn't contain that partic For procedure that has mu 'Single Product' in the XMI Indicate that the submissi 'Grouping (more than one When multiple scopes are submissions), it is indicate procedures handled in Sia is not used. When selectin multiple scopes an automa 'Grouping (more than one It is not necessary/possibl super-grouping (previousl Grouping (more Select WS/IG number:*	<ul> <li>a 'Grouping numbers' that contain the selected one to select a grouping number if the procedure cular product.</li> <li>altiple changes for a single product, select mode a delivery file and Grouping in eCTD envelope.</li> <li>on covers multiple scopes by ticking the box scope)'.</li> <li>included in a single variation (response ed with G at the end of the procedure number (for med. For procedures handled in IRIS, this indicator a procedure number for variation that contains atic tick box is filled by the system to indicate scope).</li> <li>be to select the procedure number when WS or y known as IG number) is selected.</li> <li>be than one scope): Image: Ima</li></ul>	known as IG number) has been already requested and does not appear, please contact the <u>EMA's Service</u> <u>Now</u>
Exam	<b>ple</b> : `Grouping of more that	an one scope'	

Grouping (more than one scope): 🗵

5	Click 'Generate delivery file' and save the delivery file on	The delivery file should not
5	ener cenerate denvery me and bave the denvery me on	be amended or re-named.
	vour computer.	

It is not necessary/possible to select the procedure number when WS or super-grouping (IG) number is selected.

**Human and Veterinary submissions**: In case of initial submission of a Type II 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 <u>How to pay</u>' in the pre-submission guidance. For queries on the purchase order number, please contact accountsreceivable@ema.europa.eu.

Customer number:* 🟮	Purchase Order number:* 🟮
00006	Enter purchase order number

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

Step	Description			Notes
1	Select 'var-type1b' or For Veterinary Varia select from the regula vra-e vra-i vra-s vra-r. <b>IMPORTANT</b> : Please per indicated for the <u>document</u> , regardles agreed. For scopes u guidance, always sele For grouping, please classification, regardl Select the relevant 's The 'submission d automatically selecte Select the correct mo In order to facilitate to procedure, MAHs are least two months in a variation or group of worksharing procedu to why the holder bel is suitable, by means <b>Please note that re arrangement in adv</b>	r 'var-type2 (Human only). ations Requiring Assessment atory activities list: e select the <b>timetable</b> (E, S or relevant <b>scope</b> in <u>classification</u> ss if a different timetable has be nder chapter I of the classification ect <b>vra-i</b> . select the 'longest' relevant TT ess if a different TT has been an ubmission unit' from the list. escription' Responses to R d. de: WS (worksharing of variation the planning of a worksharing advised to inform the Agency an advance of the submission of a variations to be subject to a re, together with an explanation ieves that a worksharing procee of a 'letter of intent'. <b>questing the worksharing</b> <b>vance is mandatory. The WS</b>	(VRA) R) as een oon as per greed. SI is ons) at n as dure	More information on 'Worksharing' can be found from the Regulatory Post- Authorisation Guide (search in 'human' or 'veterinary' guidance as appropriate). A <u>letter of intent template</u> must be filled and sent to the <u>EMA's Service Now</u> In case the WS number has been already requested and does not appear, please contact the <u>EMA's</u> <u>ServiceNow</u> Examples of VRA grouping: Grouping of R scopes -> vra- r, Grouping of 2 R and 2 S scopes -> vra-s
Choose a	number has to be inc	Choose a Submission-Unit*		Mode:*
var-type1b	•	initial	•	Single Product

or

Choose a submission type:*		Choose a Submission-Unit <sup>*</sup>	Choose a Submission	description*	Mode:* 🚯	
var-type1b 🔻		response	<ul> <li>Responses to RSI</li> </ul>	•	WS	•
2	As the Worksha and Nationally A ensure that the dropdown menu For human subr 'National'. For veterinary s 'Centralised/Nat	ring procedure may cont Authorised products, it is correct 'Product type' is I. mission, select between 'd ubmission, select betwee tional'.	ain both Centrally important to selected from the Centralised' and en 'Centralised' or	VET specific The difference domain stems that each WS submission ca documentation products in a Select 'Centra your WS inclu- and NAPs (inclu-	note: e for the vet s from the fact -related an contain on for all affect single packag alised/Nationa udes both CAP cluding MRP of b).	t le. l' if s r
Human WS product type		Vete	erinary WS product	type		

\*Denotes mandatory fields

Single Product

WS
Produ	ct Type: <sup>*</sup>	Product Type: <sup>*</sup>	
Centr	ralised 🔹	Centralised	•
Cen Nati	tralised onal	Centralised Centralised/National	
3	Human domain: When 'Centralised' product ty submission format cannot be be 'eCTD'. Enter the submission eCTD so number should always be the	vpe is selected, the changed and must always equence number. This e next sequential number in	The sequence number is always a numeric value (range from 0000 to 9999).
the product lifecycle. Optionally enter any related s reference related submission <b>Veterinary domain:</b>		sequence number to cross s.	If CTD is used the formet of
	When 'Centralised' product ty Submission format can be se options: "VNeeS (pharmaceu (immunological product) v3.0 product) v3.0" or "Other"	/pe is selected, the lected from the following tical product) v3.0", "VNeeS 0", "VNeeS (Biological	art II of a VMP dossier, the submission format to select is "VNeeS".

Example: Type IB worksharing (initial) for human domain

S	Submission: var-type1	Lb	
Product Type:*	Submission format:*	Sequence number: *	Related sequence:
Centralised •	eCTD -	Enter 4 digit no.	Enter related sequence
RMP included:	No	Brexit related procedure:*	⊖Yes ⊖No

**Example**: Type vra-r worksharing for a VMP – selection options

### Submission: vra-r

		Product Type* Centralised		VNeeS (Pharm	naceutical product) v3.0	Î.
		Brexi	it Pro	VNeeS (Immu	nological product) v3.0	
			_	VNeeS (Biolog	ical product) v3.0	L
Select a p	roduct*			VNeeS (pharn VNeeS (immu	naceutical product) v2.6	
4	Search for the relevant product name or EMEA product' field. The more filtered.	product by typing any product number in the e you type the more th	par 'Se e lis	t of the lect t is	For veterinary WS submissions, a sepa delivery file must be and a separate sub made for each of th Centrally Authorised included in the proc	arate XML e created, mission e d Product cedure.

	The pro visual c	duct ATC code onfirmation.	and INN are now	also shown fo	or	The package included in the submission should be the same for all products
Select a Pr	oduct:*	tractocile-EMEA/H/C/00 Tractocile-EMEA/H/C/ Orgalutran-EMEA/H/C/ Kaletra-EMEA/H/C/00 Trazec-EMEA/H/C/000	0253 000253 /000274 0368 0383	×		
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.					
WS/007- WS0417	4					
6	6 In case of initial submission of a Type II <u>Worksharing</u> 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 <u>How to</u> pay' in the pre-submission guidance. The Purchase Order Number is now a mandatory field. More information on the customer number should be provided. More information on the customer number can be found from the <u>How to</u> pay' in the pre-submission guidance. The Purchase Order Number is now a mandatory field.					information on the customer ber can be found from the <u>to pay</u> ' in the pre-submission ance. Jueries on the purchase order ber and customer number, se contact untsreceivable@ema.europa.eu
	Note: In the view of the upcoming implmentation of new fee regulation (from 1s January 2025) fields related Customer number and Purch Order number have been removed. For new Type IA, IAIN and IB variations submitted in 2024, please provide the PO number the cover letter and/or in the e					e: In the view of the oming implmentation of the fee regulation (from 1 <sup>st</sup> ary 2025) fields related to omer number and Purchase er number have been oved. new Type IA, IAIN and IB tions submitted in 2024, se provide the PO number on cover letter and/or in the eAF.
		•			Applica authori purchas similar invoice standin order c authori	nts and marketing sation holders requiring a se order number or references on their are encouraged to issue a g (blanket) purchase overing all marketing sation and/or
00006	number:	0	Enter purchase o	rder number	pharma the Age and to the Age service account	acovigilance fees levied by ancy for a given period provide such reference to ancy's accounts receivable at tsreceivable@ema.europa.eu
Gene	erate delive	ery file	Rese	t form	Alterna be prov	tively, such reference can rided here.

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

Choose a submission type:*	Choose a Submission-Unit	* Mode:*	0
var-typeib -	initial	- WS	•
	*Denotes mandatory fields		
	Submission: var-typ	e1b	
Product Type:*	Submission format:*	Sequence number:*	Related sequence:
Centralised -	eCTD -	0010	Enter related sequence
RMP included:	No No	Brexit related procedure:*	⊖Yes ⊖No
Select a Product:	Ristaben-EMEA/H/C/00	1234 3	5
	Product EMA number: EN Product short name: Rist ATC Code: A10BH01 INN: SITAGLIPTIN PHOS MAH: Merck Sharp & Do	EA/H/C/001234 aben 5PHATE MONOHYDRATE ihme B.V.	
Nitrosamine related procedure:*	○ Yes ○ No		
Please provide the na medicinal product for applied for outside of	me(s) of any centrally autho which the same change(s) a this procedure:	rised re being	
Enter product name	(s)		
	Grouping (more tha	n one scope): 🗆	
Select WS/IG number:*	WS/0846	-	
Select WS/IG number:* Customer number:*	WS/0846	se Order number:* 0	

#### Example: Complete selection for a worksharing of human CAPs

Note: If the chosen product is part of the first set of regulatory procedures onboarded to the new platform, the dropdown menu of the field '*Select WS/super-grouping (IG) number'* will display procedure number as EMA/**VR**/xxxxx

Submission Type* Vra-e	*	Submission-Unit <sup>®</sup> response	•	Submission description* Responses to RSI	Ŧ	<sup>Mode<sup>™</sup></sup> WS
			*Denotes manda	tory fields		
			Submissior	n: vra-e		
		Product Type* Centralised	Submission fo VNeeS (Pt	armaceutical product) v3.0	*	
Select a product*						
Cortavance - EMEA/V/C/0001	110		8			
Product EMA number:	EMEA/V/C/00	0110				
Product short name:	Cortavance					
ATC Code:	QD07AC					
INN:	Hydrocortison	e aceponate				
MAH:	Virbac S.A.					
Crouping (more than o	ne scope)					

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

Step	Description					Notes		
1	Select 'var-typ activities list (s Select the 'subr Select the mod In order to faci procedure, MAH least two mont variation or gro worksharing pro to why the hold is suitable, by r Please note the arrangement number must b	be1b' ubmis missio e: WS litate f ls are hs in a bup of ocedu ler be means <b>nat re</b> <b>in ad</b> be inclu	<ul> <li>or 'var-type2 from the regulatory nission type).</li> <li>sion-unit' from the list.</li> <li>NS (worksharing of variations)</li> <li>te the planning of a worksharing ure advised to inform the Agency at n advance of the submission of a of variations to be subject to a dure, together with an explanation as believes that a worksharing procedure ans of a 'letter of intent'.</li> <li>requesting the worksharing advance is mandatory. The WS polyded in the xml delivery file</li> </ul>				forma aring e Reg sation <u>of int</u> e filleo <u>ervico</u> numb	tion on <u>'</u> can be found ulatory Post- a Guide. <u>cent template</u> d and sent to the <u>eNow</u> to obtain per.
Choose a sul	omission type:*		Choose a Submission	ı-Unit <sup>*</sup>			Мос	le: <sup>*</sup>
var-type1b		•	initial		•		WS	-
			*Den	otes mai	ndatory <mark>f</mark> ields		Si	ingle Product /S
or								
Choose a subn	nission type:*	Choose	a Submission-Unit <sup>*</sup>		Choose a Submiss	ion description <sup>*</sup>		Mode:* 🚯
var-type2	•	respon	3e	•	Responses to RSI		•	WS •
*Denotes mandatory fields					Single Product WS			

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.

#### Product Type:\*

Central	ised 🔹				
Centralised					
Natior	nal				
3	If 'Product type' Nat				
format should be s					

tional 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 1<sup>st</sup> January 2019.

Product Type:\*

National 🔹	eCTD	•
	eCTD	
	Nees	
Select a Product:*	Other	e

Submission format:\*

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 is being retrieved from XEVDMP (Art. 57 database). If you are unable to find your product, please check the product 'short name' field in XEVMPD to confirm the name to use in the product selection search. If the 'short name' field in XEVMPD is empty the name is extracted from various other fields.	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.

Select a Product:*	pedia
X PENTAVAC	AVAXIM 80 U PEDIATRIC AVAXIM PEDIATRIC
× PENTAXIM	AVAXIM PEDIATRIQUE
Select worksharing number:	DAFALGAN PEDIATRIE DAFALGAN PEDIATRIQUE EFFERALGAN PEDIATRICO
Generate delivery file	ELETTROLITICA EQUILIBRATA PEDIATRICA ELETTROLITICA EQUILIBRATA PEDIATRICA BAXTER ELETTROLITICA EQUILIBRATA PEDIATRICA BIOINDUSTRIA

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.

3	¢	PENTAVAC						*
	MAH nam	e	Product full name	Country	Authorisation No.	EV Code	EMEA Product/MRP/DCF	·
	SANOFI PA	STEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459284	PRD4552363	SE/H/0153/001	^
	SANOFI PA	STEUR EUROPE	Pentavac, poudre et suspension injec	LU	2009020171	PRD4564060	SE/H/0153/001	
	SANOFI PA	STEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5458989	PRD4552360	SE/H/0153/001	
	SANOFI PA	STEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459086	PRD4552361	SE/H/0153/001	
	SANOFI PA	STEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782381	PRD4552359	SE/H/0153/001	
	SANOFI PA	STEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782282	PRD4552358	SE/H/0153/001	
~	SANOFI PA	STEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459185	PRD4552362	SE/H/0153/001	>
	7 ×	You can select all the field next to 'N individual lines to PENTAVAC	products/presentations 1AH name' field. Alterna select relevant products	by click tively, s/prese	ting to click ntations.	At least on products/p be selected	e of the resentations must	•
	MAH nam	1e	Product full name	Country	Authorisation No.	EV Code	EMEA Product/MRP/DCP	
	SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459284	PRD4552363	SE/H/0153/001	~
	SANOFI PA	ASTEUR EUROPE	Pentavac, poudre et suspension injec	LU	2009020171	PRD4564060	SE/H/0153/001	
~	SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5458989	PRD4552360	SE/H/0153/001	
~	SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459086	PRD4552361	SE/H/0153/001	
~	SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782381	PRD4552359	SE/H/0153/001	
	SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782282	PRD4552358	SE/H/0153/001	
~	SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459185	PRD4552362	SE/H/0153/001	~
Tota	<li>I Items: 44</li>	(Selected Items: 3)					>	
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.						:		
×	l	PENTAXIM					:	•
	9	Indicate if the pro recommendation	cedure is related to the Nitrosamines.	Art. 5(	3)			
I	Nitrosa	mine related procedu	re: <sup>*</sup> 🟮 🛛 Yes 🖓 No					
	10	You can provide t same change(s) a procedure using t	he name(s) of any CAPs re being applied outside he free text field	for wh e of this	ich the			
	Please medici applied	provide the name(s) inal product for which d for outside of this p	of any centrally authorised the same change(s) are b rocedure:	l eing				
Enter product name(s)								

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 <u>EMA's</u> <u>ServiceNow</u>

Select wor	ksharing number:*	ws09		
		WS/0920		
		WS/0916		
	Generate delivery file	WS/0912		
		WS/0928		
12	Click 'Generate de your computer.	elivery file' and save the	he delivery file on	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 the correct vra-s) from the type'). <b>Note:</b> the s timetable defined <u>Classification guid</u> been agreed). Select the 'submis Select the correct <b>Please note that</b> <b>arrangement in</b> a number has to be	vra submission type (v regulatory activities ubmission type should d for the selected eline (even if a different sion-unit' from the list. mode: WS (worksharin requesting the work advance is mandator included in the xml del	rra-e, vra-i, vra-r, list ('submission correspond to the scope in the ent timetable has ng of variations) csharing ry. The WS ivery file.	More information on <u>'Worksharing'</u> can be found from the Veterinary Regulatory Post-Authorisati Guide. A <u>letter of intent template</u> must be filled and sent to <u>EMA's ServiceNow</u> to obtain the WS number.
Submission Tuno		Cubmission Unit*		Single Product
vra-s	Ŧ	initial	•	ws
or				ß
Submission Type* vra-i	•	Submission-Unit <sup>*</sup> response	<ul> <li>Submission</li> <li>Response</li> </ul>	description" Mode" WS
2	As the worksharing and Nationally Aut ensure that the co dropdown menu. In this case, select	g procedure may conta horised products, it is i rrect 'Product type' is s t the 'Centralised/Natio	in both Centrally important to selected from the nal' option.	The difference for the vet domain stems from the fact that each WS related submission can contain documentation for all affect products in a single package

Product Type:\*

Centralised/National	
Centralised	

•

Centralised/National

C-1-		
3	When Product type 'Centralised/National' is selected the	If CTD is used as the format
	Submission format can be selected from the following	of part II of a VMP dossier,

A

	options: "VNeeS (pharmaceutical product) v3.0", "VNeeS (immunological product) v3.0" "VNeeS (biological product) v3.0 or "Other".					the subm select is `	iission format to "VNeeS".
Submission Tv vra-i	De <sup>v</sup>	•	Submission-Unit <sup>#</sup> response	•	Submission description* Responses to RSI	•	Mode" 🗸 🕶
				*Denotes mandatory fie	lds		
				Submission: v	ra-i		
		Pr	oduct Type* . entralised	VNeeS (Pharmace	eutical product) v3.0		
				VNeeS (Immunol	ogical product) v3.0		
Select a produ	lct*			VNeeS (pharmace	eutical product) v2.6		
			Genera	te delivery	ogical product) v2.6	Ţ	
4	Search for t the product you type the	he rele name e more	evant lead pro in the 'Select the list filter	duct by typing a a product' field ed.	any part of . The more	From 1 vetering separat must be separat each of Authori in the p packag product for eacl delivery product	January 2018, for ary IG submissions, a ce XML delivery file e created, and a te submission made for the Centrally sed Products included procedure. An identical e covering all relevant ts should be submitted n, with only the XML y file changing for each t.
Select a	Product:*	nobili	s IB4-91-EMEA/\	//C/000036	×		
		Nol	bilis IB4-91-EMEA	A/V/C/000036			
		Nol	bilis OR inac-EME	A/V/C/000062			-
Genera	ate delivery file	Nol	bivac Bb-EMEA/V	/C/000068	10		
Concre	ite delivery file	Not	billis Influenza H5 bivac Myxo-RHD-	N2-EMEA/V/C/0001	18		
		Nol	bivac L4-EMEA/V	/C/002010			
		Nol	bilis IB Primo QX-	EMEA/V/C/002802			
5	Enter/search product and	n for th select	ne WS number the WS numb	r linked to the le per.	ead CAP	If your WS available co <u>ServiceNow</u>	number is not ontact <u>EMA's</u> <u>/</u>

Product short name:	Coxevac				
ATC Code:	QI02AB				
INN: Coxiella burnetii, strain Nine Mile, Inactivated					
MAH:	CEVA Santé Animale				

# 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 'Consolidating' is now available for PAM submissions.
Choose a s	ubmission type:*	
pam-leg	•	
pam		
САР		
pam-ar		
pam-le		
pam-m	2	
pam-p4	.6 -	
pam-pa	es	
pam-re	c	
pam-so	a *	
pam-so	b	
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									
Product Ty Centralise	Product Type:*     Submission format:*       Centralised									
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	The sequence number is always a numeric value (range from 0000 to 9999)								
5	<ul> <li>Select the relevant 'PAM code' as provided in the PAM Submission form is available here. More information on the us of PAM submission form ca be found from the Post-Authorisation Guidance on PAMs – See 'How should I structure my PAM submission</li> </ul>									
Select Pam Co	Select Pam Code:* •									
No selection PASS NII Pr PASS NII I PASS NINI I PASS NINI I PASS II Pro PASS II Pro PASS INI (1 CAT CHMP 6 CAT PRAC C P46 CAT CH P46 CHMP 0 CHMP 0 PRAC CHMP	No selection         PASS NII Protocol CAT PRAC CHMP 74 Days PAM (H)         PASS NII Protocol PRAC CHMP 74 Days PAM (H)         PASS NINI Protocol CAT PRAC CHMP 74 Days PAM (H)         PASS NINI Protocol CAT PRAC CHMP 74 Days PAM (H)         PASS II Protocol CAT PRAC CHMP 74 Days PAM (H)         PASS II Protocol CAT PRAC CHMP 74 Days PAM (H)         PASS II Protocol CAT PRAC CHMP 74 Days PAM (H)         PASS II Protocol PRAC CHMP 74 Days PAM (H)         PASS II I Protocol CAT PRAC only 60 Days (H)         CAT CHMP 60 Days PAM (H)         CAT CHMP 74 Days PAM (H)         P46 CAT CHMP 74 Days PAM (H)         P46 CHMP only 60 days PAM (H)         P46 CHMP only 60 Days PAM (H)         PAC CHMP 74 Days PAM (H)									
6	For pam-sda submission type: Enter the 5-digit EPITT number as provided in the request sent by EMA.									
Enter Epit 12345	t number*									
7 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. Sequence will need to be submitted separately with it own delivery file.										
Select a P	roduct:* abraxane									
8	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'.	
Choose a s	ubmission type:*	
No selection	· · · · · · · · · · · · · · · · · · ·	
pass	×	
pass10 pass10 pass10	7n 7o 7q	
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.	
Product	Type:*	
Centra	ised 👻	
Centr	alised	
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.	
Product Ty	pe:* Submission format:*	
National	• eCTD •	
Select	a Product:* Nees	
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 <u>here</u> . More information on the use of PAM submission form can

				be found Authoris PAMs – S <u>structure</u> <u>dossier</u> '. Please n submiss provided submiss same fol letter (E	I from the Post- ation Guidance on See ' <u>How should I</u> e my PAM submission ote that the PAM ion form should be I within the eCTD ion package in the der as the cover U M1 section 1.0)	
Select Pan	Code: U					
PASS INI	(107) submission PRAC o	nly 60 Days (H)				
6	For non-initial sub- etc), for NAPs only relevant PASS Pro- If the PASS numbe- use the tick box to	missions (validation-respor , the users should now sele cedure number from the dr er is not available from the allow manual entry of the	nse, response ect the ropdown list. list, please number.	An auto- appears procedu from the FM_PAS	complete textbox with the available re numbers retrieved database of S FileMaker App	
Select Pa	ss Procedure No:	ps		×		
Select a Product:*		EMEA/H/W/ <b>PS</b> A/S/12234 EMEA/H/CN/ <b>PS</b> R/S/9998856 EMEA/H/N/ <b>PS</b> A/S/45678 EMEA/H/N/ <b>PS</b> A/S/444669 EMEA/H/N/ <b>PS</b> A/S/125436 EMEA/H/C/ <b>PS</b> A/S/34234234 EMEA/H/C/ <b>PS</b> A/S/0034				
		EMEA/H/C/ <b>PS</b> A/S/0035				
	Generate delivery file	EMEA/H/C/PSA/S/0035 EMEA/H/C/PSP/S/0066				
Select Pas	s Procedure No:*	Enter Pass Number (format EMEA/H/X/PSX/X/1234 or EMEA/H/X/PSX/X/1234.12)				
		Please tick this box if you can dropdown list and wish to ma Please ensure the number ad EMEA/H/X/PSX/X/1234 or E	not find the PAS nually enter the heres to the corr MEA/H/X/PSX/)	S number fi PASS numb ect format (/1234.12	rom the per. _ _	
7	Search for the relet the product name you type the more The list of National from XEVDMP (Art If you are unable to product 'short nam to use in the produc field in XEVMPD is various other field	vant product(s) by typing a in the 'Select a product' fie the list filtered. ly Authorised Products with 57 database). o find your product, please ne' field in XEVMPD to confi act selection search. If the empty the name is extract s.	any part of ld. The more n retrieved e check the rm the name 'short name' ed from	It is positive than one the list the products are selected it should submiss 'grouped sequence submitted own delivered to the set of the set	sible to select more e product name from o ensure that all and presentations cted. I be noted that the ions cannot be I' each eCTD or NeeS e will need to be ed separately with its very file.	

	Select a Product:*	pedia	
×	PENTAVAC	AVAXIM 80 U PEDIATRIC AVAXIM PEDIATRIC	m 1 v
×	PENTAXIM	AVAXIM PEDIATRIQUE CLEEN ENEMA PEDIATRIC	
	Select worksharing number:*	DAFALGAN PEDIATRIE DAFALGAN PEDIATRIQUE EFFERALGAN PEDIATRICO	
	Generate delivery file	ELETTROLITICA EQUILIBRATA PEDIATRICA ELETTROLITICA EQUILIBRATA PEDIATRICA BAXTER ELETTROLITICA EQUILIBRATA PEDIATRICA BIOINDUSTRIA	

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.

× PENTAVAC

	MAH name	Product full name	Country	Authorisation No	EV Code	EMEA Product/MRP/DCP	
	SANOFI PASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459284	PRD4552363	SE/H/0153/001	^
	SANOFI PASTEUR EUROPE	Pentavac, poudre et suspension injec	LU	2009020171	PRD4564060	SE/H/0153/001	
	SANOFI PASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5458989	PRD4552360	SE/H/0153/001	
	SANOFI PASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459086	PRD4552361	SE/H/0153/001	
	SANOFI PASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782381	PRD4552359	SE/H/0153/001	
	SANOFI PASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782282	PRD4552358	SE/H/0153/001	
1	SANOFI PASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459185	PRD4552362	SE/H/0153/001	-

Total Items: 44 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.

:	× PENTAVAC ~								
	V MAH name		Product full name	Country	Authorisation No	EV Code	EMEA Product/MRP/DCP		
	SANOFI P	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459284	PRD4552363	SE/H/0153/001	^	
~ ~	SANOFI P	ASTEUR EUROPE	Pentavac, poudre et suspension injec Pentavac Vacina adsorvida contra a d	LU	2009020171 5458989	PRD4564060 PRD4552360	SE/H/0153/001 SE/H/0153/001	C	
~	SANOFI P	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459086	PRD4552361	SE/H/0153/001		
~	SANOFI P	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782381	PRD4552359	SE/H/0153/001		
	SANOFI PASTEUR EUROPE		Pentavac Vacina adsorvida contra a d	PT	2782282	PRD4552358	SE/H/0153/001		
~	SANOFI PASTEUR EUROPE		Pentavac Vacina adsorvida contra a d	PT	5459185	PRD4552362	SE/H/0153/001	Ť	
Tota	l Items: 44	(Selected Items: 3)					7		
	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.								
×	× PENTAVAC >						>		
×	K PENTAXIM							>	

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** 

/	MERCK SHAR	P & DOHME BV V	arıvax puiver ocn v	vatska tili injektio	FI	18213	٢	Applicants and marketing
	1	awing Itams, 9)(Calastad Itams, 2)						authorisation holders requiring a purchase order number or
Juan	Items: 66 (Sh	owing items: o)(beletted items: 2)						similar references on their
								standing (blanket) purchase
								order covering all marketing authorisation and/or
	MAH name				Purchas	se Order n	umber* 🖪	pharmacovigilance fees levied by
1	MERCK SHAR	P & DOHME BV						the Agency for a given period and to provide such reference to
								the Agency's accounts receivable
								accountsreceivable@ema.europa.eu
		Contac	t person:*		Contact p	oerson emai	l:* 🔁	Alternatively, such reference can be provided here.
							This por	con will be the
	12	Please add the contac	ct person n	ame and em	ail addr	ess in	recinien	t of any
		the mandatory fields					commu	nication from FMA
							through	out the procedure.
				L			Please	provide the email
							addres	is of the person who is
							the res	sponsible contact for this
	Contact	person:*		Contact per	son em	ail:* 🚺	particu	lar procedure. This
							person	will be the recipient of
	Enter per	rson name		Enter email a	address		any co	mmunication from EMA
							throug	hout this procedure.
	12	Click 'Conorato dolivo	vrv filo' and	save the de	livory fi	lo on	The del	iverv file should not
	13	CIICK Generate delive	anu anu	save the de	invery ii		be ame	nded or re-named.
		your computer.						

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

Step	Description			Notes	
<ol> <li>Select the relevant submission type from the regulatory activities list e.g. MAA or var-type2.</li> <li>Select the 'submission-unit' from the list.</li> </ol>					
Choose a su	Ibmission type:*	Choose a Submission-Unit <sup>*</sup>			Mode:*
var-type1b	•	initial	•		WS 👻
		*Denotes mand	atory fields		Single Product WS
2	<ul> <li>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.</li> <li>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.</li> </ul>			Medical de number El The syster change th to 'other' H/D produ selected	evices have EMA MEA/H/D/000123. m will automatically e submission format when product with act number is

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.

#### Example: initial maa for Medical device

Select a Product:*	COOK IVF cell media-H002391	×
	Product EMA number: H002391	
	Product short name: COOK IVF cell media	
	ATC Code:	
	INN: human albumin	
	MAH: Det Norske Veritas (DNV)	
	Medical Device Related Consultation: 🗹	
Example: delivery fi	le for any subsequent submission for medica	al device

Select a Product:*	h/d ×	
	LifeGlobal Media-EMEA/H/D/004287	
	Hemoblast-EMEA/H/D/002769	
	Gems Medium Suite-EMEA/H/D/003740	
Generate delivery fil	PureSperm Wash-EMEA/H/D/002625	
	COOK IVF cell media-EMEA/H/D/002592	
	Floseal Hemostatic Matrix (Floseal VH S/D)-EMEA/H/D/0009	956

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.

Choose a submissio	on type:*	Choose a Submission-Unit*	Mode:* () Single Product	•
	Covid19 rela	ated:* 🔿 Yes 🖲 No		
		*Denotes mandatory fields		
		Submission: maa		
F	Product Type:*	Submission format:*	Sequence number: *	Related sequence:
	Centralised -	Other -	0000	Enter related sequence
F	RMP included:	No No		
	Select a Product:*	COOK IVF cell media-H002	391 🗶	
		Product EMA number: H002 Product short name: COOK ATC Code: INN: human albumin MAH: Det Norske Veritas (I Medical Device Relate	391 IVF cell media DNV) <b>d Consultation: Z</b>	

If you cannot find the 4 For post-authorisation activities, excluding the initial procedure number from the sequence for each post-authorisation procedure, please list, please contact the EMA's select the procedure number from the list of procedures **ServiceNow** Select a Product:\* Surgiflo Haemostatic Matrix Kit -Ferrosan-EMEA/H/D/02 Product EMA number: EMEA/H/D/002301 Product short name: Surgiflo Haemostatic Matrix Kit -Fer ATC Code: INN: HUMAN THROMBIN Select a Procedure Number:\* No selection • No selection EMEA/H/D/002301/IB/0013 EMEA/H/D/002301/IB/0012 ict person\* EMEA/H/D/002301/IB/0008 person name EMEA/H/D/002301/IB/0002 The delivery file should not 5 Click 'Generate delivery file' and save the delivery file on be amended or re-named. your computer.

### 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.	

Choose a submission type:*	Choose a Submission-Unit*	Mode:* 🚯	
clin-data-pub-rp 👻	initial	<ul> <li>Single Product</li> </ul>	t 👻
	*Denotes mandatory fields		
s	ubmission: clin-data-pub	-rp	
Product Type:*	Submission format:*	Sequence number: *	Related sequence:
Centralised 👻	eCTD 🔻	Enter 4 digit no.	Enter related sequence
Confirmation that the evaluation are the sar the Redaction propose the redactions: *@	clinical reports submitted for scie ne as those submitted for publicat al and Final Redacted Versions, ex	ntific :ion, in cept for	
Select a Product:*	Methylthioninium chloride Pro	veblue-EMEA/H/C/00210	
	Product EMA number: EMEA/H, Product short name: Methylthio ATC Code: V03AB17 INN: METHYLTHIONINIUM CH MAH: Provepharm SAS	/C/002108 oninium chloride Proveblue ILORIDE	
Select a Procedure Number:	No selection		

4.10.	<b>Clinical data</b>	publication fin	al version	(human	only)
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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".	'Partial' final version should only be submitted in exceptional situations.
	Select the relevant product. Select the appropriate procedure number from the predefined list. Generate the delivery file.	

Choose a submission type: C	hoose a Submission-Unit	Mode: 🛚 🚯	
clin-data-pub-fv • in	itial	<ul> <li>Single Product</li> </ul>	-
	Denotes mandatory fields		
Sub	mission: clin-data-pul	o-fv	
Product Type:*	Submission format:*	Sequence number: *	Related sequence:
Centralised -	eCTD -	0010	Enter related sequence
Clinical data for publica Version: *	tion - Final	lete I	
Select a Product:	Ilumetri-EMEA/H/C/004514	×	
	Product EMA number: EMEA/H Product short name: Ilumetri ATC Code: L04AC17 INN: TILDRAKIZUMAB MAH: Almirall S.A	ł/C/004514	
Select a Procedure Number:	No selection	•	
	No selection		
	EMEA/H/C/004514/II/0	005/G	
Generate delivery fil	e EMEA/H/C/004514/000	0	

### 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	

Choose a submis	sion type:*	Che	oose a Submission-Unit	•	Mode:*	8	
rmp	-	init	ial		▼ Single Proc	duct	-
		*[	Denotes mandatory fields				
			Submission: rmp				
	Product Type:*		Submission format:*		Sequence number: *		Related sequence:
	Centralised -		eCTD -		0010		Enter related sequence
	RMP version Number						
	13						

## 4.12. Raw Data submission (Pilot – for human only)

Step	Description	Notes
1	Select 'Raw Data submission' from the regulatory activities list (submission type). Product type is always 'centralised' and the submission format is always 'Other'. Please select the product by typing the EMA product number (the product number H00123 or H/C/001234 can be searched for and selected). Once you have selected the product and confirmed that the details are correct, please click 'Generate delivery file' and save the delivery file on your computer.	The EMA product number is available on the Eligibility confirmation letter as 'Product Reference'. The Eligibility Confirmation Letter indicates Product number e.g. H0002271. Product numbers start H/C for human CAPs. The delivery file should not be amended or re-named.
2	See section 14. Saving the XML delivery file and preparing the submission package	

Submission Type* Raw Data submission	n T

#### Submission: Raw Data submission

\*Denotes mandatory fields

	Product Type* Centralised	Ŧ			Submission format* Other	Ŧ	
Select a product* Enter product name of	or number						
			Generate delivery file	Reset form			

### 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.

Choose a submission type:*		Choose a Submissi	on-Unit:*		Cho	oose a Submission descr	riptior	*	Mode: 🔭 🖪	•
referrals	•	response		•	No	selection		•	Single Produ	uct 💌
				Denotes mai	ndato	ory fields				
			ş	Submissi	on:	referrals				
	Referra	ls Article <sup>*</sup>	Product Typ	e:*		Submission format:*		Sequence	number:*	
	Nothing	selected 🔹	Centralised	-		eCTD -		Enter 4 dig	jit no.	
		Select a Re	eferral: *	Enter EM	A Ref	erral no. or name				
				Procedure r EMA Referr	name al Nu	:: mber:				
		Select a Product	(CAPs): <sup>*</sup>	Enter EM/	A no.	or product name				
				Product EM Product sho MAH:	A nui ort na	mber: ame:				
				Custome	r nu	mber:* 0		Purchase	Order number:	0
E	Is this	fee related ?		00006				Enter purc	hase order num	ber

# 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 Select the 'submission- The submission mode is	`Referrals' unit' from the list. s always single product.	Requests for re-examination of an outcome of the Referral procedure should be submitted via the eSubmission Gateway using the submission unit 're- examination'.
Choose a s	ubmission type: <sup>*</sup>	Choose a Submission-Unit <sup>*</sup>	Mode:* Single Product
1.1	If submission unit is "re response by selecting a description	esponse", then indicate the type of value from the submission	For both Human & Veterinary submissions

Choose a s	ubmission type:*	Choose a Submiss	ion-Unit*	Choose a Submiss	ion description*	Mode:*
referrals		✓ response		- No selection	-	Single Product 👻
		*Denotes mandato	ry fields referrals	No selection Responses to RS List of Question List of Outstand	SI s ing Issues	
2	If you select Ar The Product ty changed and m Enter the subm	ticle20 from the dr vpe and the subm ust always be `Cer ission eCTD seque	ropdown ission fo ntralised' nce numl	list. rmat cannot be and `eCTD'. ber.	The sequent always a nu (range from	ce number is meric value 0000 to 9999)
		Subm	ission: I	referrals		
Referral	s Article <sup>*</sup>	Product Type:*		Submission format:	* Seque	ence number: *
Article20	•	Centralised	•	eCTD	• 0057	
3	If you are select from the dropd 'Centralised'. If format cannot l Enter the subm	ting Article5(3), A own list, select the Centralised is sele be changed and m ission eCTD seque	rticle31 o procedu ected the ust alway nce numl	or Article107i re type submission rs be 'eCTD'. ber.	The sequent always a nu (range from	ce number is meric value 0000 to 9999)
		Subm	ission:	referrals	* _	
Referra	als Article	Product Type:		Submission format:	Seque	nce number:
Articles	(3)	Centralised	• [	eciD	Enter	sequence no.
Or						
Referral	5 Article <sup>*</sup>	Product Type:*		Submission format	t: <sup>*</sup> Sequ	uence number: *
Article31	-	Centralised	•	eCTD	• Ente	r sequence no.
Or						
Referral	5 Article <sup>*</sup>	Product Type:*		Submission format	:* Sequ	ence number: *
Article10	7i 🔹	Centralised	•	eCTD	• Enter	sequence no.
4	Select the reference referral number more you type Avoid using das	erral procedure by r or the product/act the more the selec sh (-) in the search	<ul> <li>typing</li> <li>tive subst</li> <li>tion is fil</li> <li>field.</li> </ul>	the article, the cance name. The tered.	Please note does not rea symbol. Plea the referral example 12	that the search cognise dash (-) ase search using number for 34.

Select a Referral: *	123 ×
	EMEA/H/A29(4)/1123-Gluscan_A29(4)/1123
	EMEA/H/A29(4)/1238-Levact_A29(4)/1238
alact a Braduct/CADc).*	EMEA/H/A31/1232-Strong opioids_A31/1232
elect a Product(CAPS).	EMEA/H/A31/1238-Fibrates_A31/1238

or

Select a Referral: *       opio       x         EMEA/H/A31/1232-Strong opioids_A31/1232         EMEA/H/A31/1232-Strong opioids_A31/1232         EMEA/H/A31/1232-Strong opioids_A31/1232         EMEA Referral Number:         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.         Select a Product:       at         Helicobacter Test INFAI-EMEA/H/C/000140         Pylobactell-EMEA/H/C/000232         Tractoile-EMEA/H/C/000235         Nonsfact-EMEA/H/C/000255         Nonsfact-EMEA/H/C/000348         Actrapid-EMEA/H/C/000427         Competat-EMEA/H/C/000427         Competat-EMEA/H/C/000902         RoActerinz=EMEA/H/C/000935         Tandemart-EMEA/H/C/000932         RoActerinz=EMEA/H/C/000931
EMEA/H/A31/1232-Strong opioids_A31/1232         EMA Referral Number:         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.         Select a Product:         act         Pylobactel-EMEA/H/C/000151         Refacto AF-EMEA/H/C/000232         Actor-EMEA/H/C/000253         Actor-EMEA/H/C/000242         Actor-EMEA/H/C/000255         Nonafact-EMEA/H/C/000427         Competact-EMEA/H/C/000955         Tandemact-EMEA/H/C/000925         RoActemra-EMEA/H/C/000925         Roactemra-EMEA/H/C/000925         Tandemact-EMEA/H/C/000925         Tandemact-EMEA/H/C/000935         Tandemact-EMEA/H/C/000935         Tandemact-EMEA/H/C/000935         Tandemact-EMEA/H/C/000935         Tandemact-EMEA/H/C/000935         Tandemact-EME
EMEA/H/A31/1232-Strong opioids_A31/1232         FMA Referal Number:         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.         Select a Product:         att         Heikcobacter Test INFAI-EMEA/H/C/000140         Pylobactell-EMEA/H/C/000232         Generate delvery file         Tractocile-EMEA/H/C/000233         Actor-EMEA/H/C/000242         Actor-EMEA/H/C/000427         Comperate-EMEA/H/C/000925         Tandemact-EMEA/H/C/000925         Tandemact-EMEA/H/C/000921         RoActemra-EMEA/H/C/000925         Topotecan Actavis-EMEA/H/C/000131
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.         Select a Product:       act         Helcobacter Test INFAI-EMEA/H/C/000140         Pylobactell-EMEA/H/C/000232         Tractocile-EMEA/H/C/000233         Actor-EMEA/H/C/000235         Nonafact-EMEA/H/C/000244         Actor-EMEA/H/C/000680         Mepart-EMEA/H/C/000680         Mepart-EMEA/H/C/000055         Trademart-EMEA/H/C/000055         Trademart-EMEA/H/C/000680         Mepart-EMEA/H/C/000081         RoActemra-EMEA/H/C/000081         RoActemra-EMEA/H/C/000802         RoActemra-EMEA/H/C/000802         RoActemra-EMEA/H/C/000802         RoActemra-EMEA/H/C/000802         RoActemra-EMEA/H/C/000802         RoActemra-EMEA/H/C/000802         RoActemra-EMEA/H/C/000802         Topotecan Actavis-EMEA/H/C/001031
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.         Select a Product:         act         Helicobacter Test INFAI-EMEA/H/C/000140 Pylobactell-EMEA/H/C/000232         Generate delivery file         Tractocile-EMEA/H/C/000232         Tractocile-EMEA/H/C/000233         Actos-EMEA/H/C/000235         Nonafact-EMEA/H/C/000235         Nonafact-EMEA/H/C/000235         Nonafact-EMEA/H/C/000235         Tactocile-EMEA/H/C/000235         Tactocile-EMEA/H/C/000235         Nonafact-EMEA/H/C/000235         Tademact-EMEA/H/C/000237         Competact-EMEA/H/C/000655         Tademact-EMEA/H/C/000635         Tademact-EMEA/H/C/000690         Mepact-EMEA/H/C/000092       RoActemra-EMEA/H/C/0000911
Select a Product:*       act         Heicobacter Test INFAI-EMEA/H/C/000140       Pylobactell-EMEA/H/C/000151         Refacto AF-EMEA/H/C/000232       Tractocile-EMEA/H/C/000233         Actos-EMEA/H/C/000285       Nonafact-EMEA/H/C/000348         Actrapid-EMEA/H/C/000424       Actrapid-EMEA/H/C/000427         Competact-EMEA/H/C/000655       Tandemact-EMEA/H/C/000635         Tandemact-EMEA/H/C/000630       Mepact-EMEA/H/C/000635         Topotecan Actavis-EMEA/H/C/000031       Please include the SAP         Customer number is prefilled using the MAH       Please order number if
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       Please include the SAP Customer number if
Generate delivery file       Pylobacteli-EMEA/H/C/000232         Tractocile-EMEA/H/C/000253       Tractocile-EMEA/H/C/000253         Actos-EMEA/H/C/000285       Nonafact-EMEA/H/C/000424         Actrapid-EMEA/H/C/000427       Competact-EMEA/H/C/000680         Mepact-EMEA/H/C/000082       RoActemra-EMEA/H/C/0000955         Topotecan Actavis-EMEA/H/C/001031       Topotecan Actavis-EMEA/H/C/001031         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       Please include the SAP Customer Number and purchase order number if
Generate delivery file       ReFacto AF-EMEA/H/C/000232         Tractocile-EMEA/H/C/000285       Actos-EMEA/H/C/000285         Nonafact-EMEA/H/C/000348       Actrapid-EMEA/H/C/000424         Actrapid-EMEA/H/C/000655       Tandemact-EMEA/H/C/000655         Tandemact-EMEA/H/C/000802       RoActemra-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/0001031       Please include the SAP         Customer number is prefilled using the MAH       Please order number if
Generate delivery file       Tractocile-EMEA/H/C/000253         Actos-EMEA/H/C/000285       Nonafact-EMEA/H/C/000348         Actrapid-EMEA/H/C/000424       Actrapid-EMEA/H/C/000427         Competact-EMEA/H/C/000655       Tandemact-EMEA/H/C/000655         Tandemact-EMEA/H/C/000802       RoActemra-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/001031       Please include the SAP Customer Number and purchase order number if
Actos-EMEA/H/C/000285         Nonafact-EMEA/H/C/000424         Actrapia-EMEA/H/C/000427         Competact-EMEA/H/C/000655         Tandemact-EMEA/H/C/000680         Mepact-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/001031         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       Please include the SAP Customer Number and purchase order number if
Nonafact-EMEA/H/C/000348         Actrapid-EMEA/H/C/000424         Actrapia-EMEA/H/C/000427         Competact-EMEA/H/C/000655         Tandemact-EMEA/H/C/000680         Mepact-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/00031         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
Actrapid-EMEA/H/C/000424         Actrapid-EMEA/H/C/000427         Competact-EMEA/H/C/000655         Tandemact-EMEA/H/C/000802         RoActemra-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/001031         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       Please include the SAP Customer Number and purchase order number if
Actraphane-EMEA/H/C/000427         Competact-EMEA/H/C/000655         Tandemact-EMEA/H/C/000680         Mepact-EMEA/H/C/000802         RoActemra-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/001031         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       Please include the SAP Customer Number and purchase order number if
Competact-EMEA/H/C/000655         Tandemact-EMEA/H/C/000680         Mepact-EMEA/H/C/000802         RoActemra-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/001031         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       Please include the SAP Customer Number and purchase order number if
Tandemact-EMEA/H/C/000680         Mepact-EMEA/H/C/000802         RoActemra-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/001031         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       Please include the SAP Customer Number and purchase order number if
Mepact-EMEA/H/C/000802         RoActemra-EMEA/H/C/000955         Topotecan Actavis-EMEA/H/C/001031         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       Please include the SAP Customer Number and purchase order number if
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       Please include the SAP Customer Number and purchase order number if
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       Please include the SAP Customer Number and purchase order number if
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 Please include the SAP Customer Number and purchase order number if
customer number from EMA product database; however, it can be manually changed if it is incorrect.applicable for fee related Referral procedures.Mandatory Purchase Order number must be included.Referral procedures.
Select a Product(CAPs): Applicants and marketing authorisation holders requiring a purchase order number or similar references on their invoice are encouraged to issue a standing (blanket) purchase order covering all marketing
Customer number: ●     Purchase Order number: ●     authorisation and/or     pharmacovigilance fees levied by     the Agency for a given period     and to provide such reference to     the Agency's accounts receivable     service at     accountsreceivable@ema.europa.e
Generate delivery file Reset form be provided here.
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/PRAC 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 Submissi	ion type 'Referral	ls′			
	Select the 'subr	nission-unit' fron	n the list.			
	The submission	mode is always	single prod	uct.		
Choose a s	ubmission type:*	Choose a Si	ubmission-Unit	*	Мо	de:*
referrals		▼ initial		•	Sin	gle Product 👻
1.1	If submission uresponse by sel description	nit is "response", ecting a value fro	, then indica om the subi	ate the type of mission	For both H Veterinary	uman & submissions
Choose a s	ubmission type:*	Choose a Submi	ssion-Unit*	Choose a Submissio	on description*	Mode:*
referrals	domission (ppc.	response	Solution Child	No selection	•	Single Product •
		*Denotes manda	atory fields	No selection Responses to RSI	L _	
		Submission	1: referrals	List of Questions List of Outstandin	ng Issues	
2	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					
Referral	Article <sup>*</sup>	Product Type:*	:	Submission format:	:* Sequ	uence number: *
Article5(3	) -	National	•	eCTD	• Ente	r sequence no.
3	If you select Ar Paediatric) from always 'Nationa format may be	ticles 13, 16C-1- the dropdown li l' for these proce changed to eCTD	C, 16-C-4, 2 ist the prode dures. The D, NeeS or C	29(4), 30 or 29 uct type is submission Other		
		Subr	nission: re	eferrals		
Referrals	Article <sup>*</sup>	Product Type: <sup>*</sup>	S	ubmission format:*	Seque	nce number: *
Article13	•	National	- e	CTD 🔻	Enter s	equence no.
				eCTD		
				Nees		
	Select a R	eferral: <sup>*</sup> Ent	or FMA Rofess	Other		
4	Enter the subm always be the m If the submission the sequence m	ission sequence i ext sequential nu on is in 'other' for umber field	number. Th umber in th rmat you m	is number should e product lifecycle ay enter 0000 in	e.	

5	Select th article, th name. Th Avoid usi	e correct referral procedure num he referral number or the produc ne more you type the more the s ing dash (-) in the search field.	ber by typing the t/active substance election is filtered.	Please note that the search does not recognise dash (-) symbol. Please search using the referral number for example 1234.
Select a Ref	erral:*	107i		
a Product(N Generate	IAPs):* delivery file	EMEA/H/A107i/1352-Tetrazepam_A10 EMEA/H/A107i/1357-Cyproterone Acet. (2mg/0.035mg)_A107i/1357 EMEA/H/A107i/1363-Flupirtine_A107i/ EMEA/H/A107i/1376-Hydroxyethyl star HES_A107i/1376 EMEA/H/A107i/1373-Numeta_A107i/1 EMEA/H/A107i/1395-Methadone contai povidone_A107i/1395	7i/1352 ate/Ethinylestradiol 1363 rch - 373 ning	
6	Search for the production you type The list of from XEV	or the relevant product(s) by typ uct name in the 'Select a produc the more the list filtered. of Nationally Authorised Products /DMP (Art, 57 database).	ing any part of t' field. The more with retrieved	It is possible to select more than one product name from the list to ensure that all products and presentations are selected.
		Select a Product:*	pedia	
×	PENTAVAC		AVAXIM 80 U PEDIATR AVAXIM PEDIATRIC	IC
×	PENTAXIM		AVAXIM PEDIATRIQUE	BIC
		Select worksharing number:*	DAFALGAN PEDIATRIE DAFALGAN PEDIATRIQ EFFERALGAN PEDIATR ELETTROLITICA EQUIL	UE ICO IBRATA <b>PEDIA</b> TRICA
		Generate delivery file	ELETTROLITICA EQUILI ELETTROLITICA EQUILI	IBRATA PEDIATRICA BAXTER
7	Expand t field with and selec Multiple selection	the product details by clicking an the selected product name and ct the relevant products/presenta criteria may be used to filter the	ywhere in the proceed to filter ations. product	

MAH nam						
	le	Product full name	Country	Authorisation No.	EV Code	EMEA Product/MRP/DCF
SANOFI PA		Pentavac vacina adsorvida contra a d	PT	5459284	PRD4552363	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac, poudre et suspension injec	LU	2009020171	PRD4564060	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5458989	PRD4552360	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459086	PRD4552361	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782381	PRD4552359	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782282	PRD4552358	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459185	PRD4552362	SE/H/0153/001
Items: 44 8	You can select the field next t individual lines	all products/presentations o 'MAH name' field. Alterna to select relevant products	by click tively, s/prese	king to click ntations.	At least one products/pr be selected	e of the esentation must
×	PENTAVAC					
MAH nam	ne	Product full name	Country	Authorisation No	. EV Code	EMEA Product/MRP/DCP
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459284	PRD4552363	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac, poudre et suspension injec	LU	2009020171	PRD4564060	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5458989	PRD4552360	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	5459086	PRD4552361	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782381	PRD4552359	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	PT	2782282	PRD4552358	SE/H/0153/001
SANOFI PA	ASTEUR EUROPE	Pentavac Vacina adsorvida contra a d	РТ	5459185	PRD4552362	SE/H/0153/001
	all products/pr sequence has	esentations for which a sin been prepared for.	gle sub	mission		
	PENTAVAC					:
	PENTAXIM					:
10	If the procedur herbal product product name applicant/comp	re contains non-authorised (s) tick the box and provide in the `Product name' field	produc e a sing and the	t(s) or Ile `lead' e	Note: Do n duplicate/re product det text field if	not epeat the 'lead' tails in the free they are already
	multiple produ additional proc	pany name in the 'Applican cts are included, the produ lucts can be included in the	t name ct detai free te	' field. If Is for the ext field	entered in 1 field. <b>Note:</b> If an products ar same delive not provide details. The included in will be cons `lead' produ	ine Product name re included in the ery file, please do e Lead product e 'first' NAP the delivery file sidered as the uct.
🕅 Non-a	multiple produ additional proc	pany name in the 'Applican' cts are included, the produ lucts can be included in the (s)/Herbal product(s)	t name ct detai	' field. If Is for the ext field	entered in f field. <b>Note:</b> If an products ar same delive not provide details. The included in will be cons 'lead' produ	y authorised re included in the ery file, please do the delivery file sidered as the act.
Non-a	multiple produ additional proc	cts are included, the produ ducts can be included in the (s)/Herbal product(s)	t name ct detai free te	' field. If Is for the ext field ter lead product	entered in f field. <b>Note:</b> If an products ar same delive not provide details. The included in will be cons 'lead' produ	y authorised re included in the ery file, please do e Lead product e 'first' NAP the delivery file sidered as the act.

500 characters remaining.

#### Example:

WonderTa	ablet 10mg	Product name:*	WonderPill 1	Omg
Wondercapsule 13mg		Applicant name:*	Drugs Ltd	
11	Provide the contact per-	son details for the refe	rral.	<b>Note:</b> Please provide the contact details for the contact person during the referral procedure
Contact	person*	Phone number*		Contact email*
Enter per	son name	Use format +countrycode xxx	XXXXXXX	Enter email
12	If the referral procedure the box 'Is this fee relat Please provide the EMA the purchase order num	is fee related, please t ed?' to expand the sect SAP Customer number ber	tick For tion. nur and plea acc	queries on the purchase order nber and customer number, ase contact ountsreceivable@ema.europa.eu
		Customer number:* 🗿		Purchase Order number: 🟮
🗹 Is this fe	ee related ?	00006		Enter purchase order number
13	Click 'Generate delivery	file' and save the deliv	very file on	The delivery file should not be amended or re-named.

# **5.3.** Create delivery file for Veterinary Referrals reviewed by the CVMP<sup>1</sup> for Centrally or Nationally Authorised Products

Step	Description		Notes
1	Click on the 'Veterinary' b submissions domain. Select Submission type 're Select the 'submission-un Select relevant submission additional-information. The submission mode is d 'Single product.'	utton to enter the vet eferrals'. it' from the list. n-unit i.e. response or isabled and shows always	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.
Choose	a submission type: <sup>*</sup>	Choose a Submission-Unit:*	Mode: * 👩
referrals	•	No selection	▼ Single Product ▼
		No selection	
		initial	
		validation-response	
		response	
		additional-info	
	Referrals Article *	closing	on format: *
	Referrats Article	consolidating	on tornat.
	Nothing selected	corrigendum	•
		reformat	
		1	

<sup>1</sup> Committee for Medicinal Products for Veterinary Use. For more information concerning referrals reviewed by the CVMP, see the <u>Veterinary Regulatory Referral Guide</u>.

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

Choose a submission type:*		Choose a Submission-Unit*	Choose a Submission description*	Mode:* 🚯	
referrals	•	response	No selection -	Single Product	
			No selection		
		*Denotes mandatory fields	Responses to RSI		
		Submission: referrals	List of Questions List of Outstanding Issues		

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:

Note that Article 45 procedure submissions are no longer possible.

- Article 82 -> Centralised or National
- Article 82 PhV -> Centralised or National
- Article 130(4) -> Centralised (only)
- Article 141(1) -> Centralised/National (only)
- Article 70(11) -> National (only)
- Article 58 -> National (only)

#### Submission: referrals

	Referrals Article *	Product Type: *	Submission format: *
	Article82 -	Centralised -	VNeeS -
ſ	Article82		
	Article82 PhV		
	Article130(4)	EMEA-V-A	
	Article141(1)	EMA Referral Number: EMEA-V	/
	Article70(11)	Link herenar humber. Linkk h	
P	Article58(4)	Enter Product or referral nam	ne
	MAH Name:*	Enter MAH Name	

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', 'National' or 'Centralised/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.

Product Centrali Centra Nation Centra	Type: * sed ▼ lised al lised/National			
4	Select Submiss either be 'VNee	sion format from the drop eS' or 'Other'.	odown. This can	If CTD is used for part II of a VMP dossier, the submission format to select is "VNeeS".
	S	ubmission: referrals		
Referrals	Article *	Product Type: *	Submission format:	•
Article70(:	-	National •	VNeeS	-
			Other	
5	In the Referra assigned to th format: EMEA-	l field, <b>enter</b> the speci is procedure. This is a V-A-123.	fic referral number 3 digit number in	Enter the three digits in the <b>number</b> field.
6	In the Product, name assigned on the letter fr procedure and containing zinc	referral name field, enter to this procedure. This r om the Agency regarding a List of Questions (eg. ' oxide").	<b>er</b> the specific name can be found g the Start of the WMPs for pigs	Enter the product or referral name in the <b>free text</b> field.
7	In the MAH Na authorisation h submission rela	me field <b>enter</b> the name older of the product to wates.	of the marketing which the	Enter the MAH name in the <b>free text</b> field.
	Referral:*	EMEA-V-A-123		
		EMA Referral Number: EMEA-V	-A-123	
Product/I	eferral name:*	VMPs for pigs containing zinc	oxide	
	MAH Name:*	VetCompany Ltd		)
8	Confirm the de file' and save t	tails are correct. Click 'G he delivery file on your c	enerate delivery 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 <u>PSUR Repository website</u>.

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

Step	Description	Notes
1	Select Domain 'Veterinary'	
Huma	n 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	
MRL		
MRL ext	ension	
MRL ext	rapolation	
MRL ful		
MRL mo	dification	
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'.

### 7.1. Create delivery file for MRL submissions

Choose a S	Choose a Submission-Unit:*		
No selection	•		
No select	ion		
initial			
validatio	validation-response		
response			
additional-info			
closing			
consolidating			
corrigendum			
reformat			
Δ	For response submiss		
-			

## For response submissions, please select the relevant Submission description from the dropdown list

Choose a	Submission-Unit:*	Choose a Submission description:	•
response	•	No selection	-
*Denotes	s mandatory fields	No selection List of Questions List of Outstanding Issues After Provisional MRL	
5	Select the substance by typ selecting from the list of av	ping the name in field and vailable substances	If you are unable to find the substance, please contact <u>EMA's</u> <u>ServiceNow</u>
6	For MRLs the Submission F field is automatically filled a the user.	ormat is always VNeeS. This and cannot be changed by	
7	Select the relevant Procedu part of the procedure numb relevant procedure.	t is 'initial' the procedure	
	number is not yet available number not assigned".	Please tick "Procedure	

Procedure number:

No selection	-
No selection	
EMEA/V/MRL/005009/FULL/0002	
EMEA/V/MRL/005009/FULL/0001	

or

-		- *
Procedur	e num	ber:

Enter procedure No.

Procedure number not assigned: 🗹

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



### 8. Create delivery file screen – ASMF

	Human		Veterinary
Choose a submis	sion type:*	Choose a Submission-Unit*	Mode:* 👩
asmf	•	No selection	▼ Single Product ▼
		*Denotes mandatory fields	
		Submission: asmf	
	Product Type:*	Submission format:*	Sequence number: *
	Centralised -	eCTD -	Enter 4 digit no.
	Select ASMF:*	Enter ASMF id. or substance	e name
Please tick this box if you cannot find the ASMF number from the dropdown list and wish to manually enter the ASMF number. Please ensure the number adheres to the correct format - EMEA/ASMF/XXXXX or EU/ASMF/XXXXX			
		ASMF number:	
	Select a Product:*	Enter EMA no. or product n	ame
		Product EMA number: Product short name:	
		The sector of the first	

	Human	Veterinary		
Choose a submi	ission type:*	Choose a Submission-Unit* Mode:* 3		
asmf	•	initial		
*Denotes mandatory fields				
Submission: asmf				
	Product Type:*	Submission format:*		
	Centralised	▼ VNeeS ▼		
	Select a Product:*	Inflacam-EMEA/V/C/002497		
		Product EMA number: EMEA/V/C/002497 Product short name: Inflacam		
	Select ASMF:*	Enter ASMF id. or substance name		
		Please tick this box if you cannot find the ASMF number from the dropdown list and wish to manually enter the ASMF number. Please ensure the number adheres to the correct format - EMEA/ASMF/XXXXX or EU/ASMF/XXXXX		
		ASMF number:		
Sele	ect a Procedure Number:	No selection -		

### 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.

Step	Description	Notes
1	Select Submission type 'ASMF'	
Choos asmf	e a submission type: <sup>*</sup>	
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).
Choose a S	ubmission-Unit <sup>*</sup>			
initial		•		
No select	tion			
initial				
validatio	n-response			
response				
additiona	il-info			
t closing:				
consolida	ting			
corrigend	lum			
reformat				
3 Mode:* Various CAPS Single Prov various CA various CA	Select the 'N Sing Variant	4ode' Jle ous CAPs ous CAPs and	d NAPs	
4	Human dor	main:		The sequence number is
-	The Product type and the submission format cannot be changed and must always be 'Centralised' and 'eCTD'. Enter the submission eCTD sequence number. <b>Veterinary domain:</b> The Product type cannot be changed and must always be 'Centralised'. The submission format may be chosen from the two options: 'VNeeS' or 'Other'.			always a numeric value (range from 0000 to 9999) Select 'Other' for ASMFs in CTD structure.



Submission: asmf				
Product Type:*	Submission format:*	Sequence number: *		
Centralised -	eCTD •	Enter sequence no.		

### Veterinary ASMF opions:

Submission: asmf			
	Submission format:*		
-	VNeeS -		
	VNeeS		
	Other		
	Submissio		

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 <u>EMA ServiceNow</u> 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:

5

Select ASMF:*	eu <mark>/</mark> /ASMF/01083-AMIKACIN SULFATE	
	EU/ASMF/01083-AMIKACIN SULFATE	
elect a Product:*	EU/ASMF/01148-BORTEZOMIB	
	EU/ASMF/00032-CINACALCET	
	EU/ASMF/00068-DAPTOMYCIN	
	EU/ASMF/00053-DIMETHYL FUMARATE	
	EU/ASMF/00048-EDOTREOTIDE	

#### ASMF Manual field entry:


which have not been authorised yet.

#### Human product selection:

Select a Product:*	act	
	Helicobacter Test INFAI-EMEA/H/C/000140	<b>^</b>
	Pylobactell-EMEA/H/C/000151	
	ReFacto AF-EMEA/H/C/000232	-
Generate delivery file	Tractocile-EMEA/H/C/000253	
	Actos-EMEA/H/C/000285	
	Nonafact-EMEA/H/C/000348	
	Actrapid-EMEA/H/C/000424	
	Actraphane-EMEA/H/C/000427	
	Competact-EMEA/H/C/000655	
	Tandemact-EMEA/H/C/000680	
	Mepact-EMEA/H/C/000802	
	RoActemra-EMEA/H/C/000955	
	Topotecan Actavis-EMEA/H/C/001031	-

Veterinary product selection for ASMF:

Select a P	roduct:*	033				
		-V0004 Metacar	<b>033</b> m-EMEA/V/C/000 <b>033</b>			
Generate	e delivery file		Reset form			
Select a Proc	edure Numb	er:	No selection		•	
7	Select p	rocedu	re number from predefine	ed list.		
Select a Pro	elect a Produc	ct: <sup>*</sup> per:	EMEA/V/C/000033/II/0123/G EMEA/V/C/000033/IA/0122 EMEA/V/C/000033/IA/0121 EMEA/V/C/000033/IB/0120 EMEA/V/C/000033/X/0119 EMEA/V/C/000033/II/0118/G EMEA/V/C/000033/IB/0117 EMEA/V/C/000033/IB/0120		•	
8 Click 'Generate delivery file' and save the delivery file on the vour 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 Submissi single product.	on type `	PMF'. Submiss	ion mode is always		
Choose a s	ubmission type:*	С	hoose a Submissio	on-Unit <sup>*</sup>		Mode:*
pmf		• ir	nitial	•		Single Product 🔹
2	Select relevant	Submissi	on-Unit			
Choose a S	ubmission-Unit <sup>*</sup>					
initial		•				
No selec	tion					
initial						
validatio	n-response	-				
response	9					
additiona	al-info					
t closing						
al consolida	ating					
- corrigen	aum					
reformat						
3	The Product typ	e and the	e submission fo	ormat cannot be	The sea	quence number is
	changed and mu	ust alway	s be 'Centralis	ed' and `eCTD'.	always	a numeric value
	Enter the submi	ssion eC	TD sequence n	umber.	(range	from 0000 to 9999)
		Submi	ssion: pmf			
		Subini	ssion, prin			
Product 1	ype:*	Submiss	sion format:*	Sequence numb	er: *	
Centralis	ed 🔹	eCTD	-	Enter sequence n	D.	
4	Select the PMF	procedur	e by typing th	e PMF number. The		
	more you type t	he more	the list is filter	red.		

Select a PM	F Holder:*	pmf	
		-EMEA/H/PMF/000001/04/	
		-EMEA/H/PMF/000002/04/	
		-EMEA/H/PMF/000003/04/	
Genera	ate delivery file	-EMEA/H/PMF/000004/04/	
		-EMEA/H/PMF/000007/04/	
		-EMEA/H/PMF/000008/05/	
		-EMEA/H/PMF/000009/05/	
		-EMEA/H/PMF/000010/06/	
		-EMEA/H/PMF/000011/06/	
		-EMEA/H/PMF/000012/07/	
		-EMEA/H/PMF/000013/07/	
© Euro	pean Medicines	-EMEA/H/PMF/000014/08/	
G Luit	pourrecontrac	-EMEA/H/PMF/000015/09/	
5	Click 'Gene	rate delivery file' and save the delivery file or	The delivery file should not be amended or re-named.
	your comp	uter.	

## **10.** Create delivery file screen – VAMF and VAMF-var (Veterinary only)

A new submission type has been added in line with a new procedure type introduced in VMP-Reg for **veterinary vaccine antigen master file** (VAMF) certification and variation on VAMF. More information on the procedure can be found <u>here</u>.

#### **10.1.** Create delivery file for VAMF and/or VAMF-var

Step	Description		Notes
1	Select Submission type 'V	AMF' or VAMF-var.	
Choose a	submission type:*	Choose a Submission-Unit:*	
vamf	•	No selection	•
2	Select relevant Submissio	n-Unit	
Choose a	Submission-Unit:*		
No selection	on	•	
No sele	ction		
initial			
validati	on-response		
respons	se		
addition	nal-info		
closing			
consoli	dating		
corrige	ndum		
reforma	at	-	

3	The submission always be 'VNe	format cannot be changed and must eS'.	
4	<b>VAMF</b> Enter the VAMF text field. The V to the start of t	number in the correct format in the free /AMF number will be communicated prior he procedure.	The number must follow the format: EMEA/V/VAMF/xxxx
Submiss	ion format: <sup>*</sup>	VNeeS	~
VAI	1F number:*	EMEA/V/VAMF/1234	
		Please ensure the number adheres to the correc EMEA/V/VAMF/XXXX	t format -
5	VAMF variatio Enter the VAMF in the free text will be commun	<b>n</b> procedure number in the correct format field. The VAMF-var procedure number icated prior to the start of the procedure.	The number must follow the format: EMEA/V/VAMF/XXXX/VRA/YYYY or EMEA/VAMF/XXXX/VNRA/YYYY
Sul	omission format:*	VNeeS	-
VAMF procedure number:*		EMEA/V/VAMF/1234/VRA/2022 Please ensure the number adheres to the c EMEA/V/VAMF/XXXX/VRA/YYYY or EMEA/V/VAMF/XXXX/VNRA/YYYY	orrect format -
6	Add the MAH na fields	ame and the Substance in the free text	
MAH Name	The Pharr	na Company Ltd	
Substance	Substance	2	
7	Click 'Generate your computer	delivery file' and save the delivery file on	The delivery file should not be amended or re-named.

## **11.** Create delivery file screen – vPTMF and vPTMF-var (Veterinary only)

A new submission type has been added in line with a new procedure type introduced in VMP-Reg for veterinary **vaccine platform technology master files** (VPTMF) and variation on vPTMF. More information on the procedure can be found <u>here</u>.

#### **11.1.** Create delivery file for vPTMF and/or vPTMF-var

Step	Description	Notes
1	Select Submission type 'vPTMF' or vPTMF-var.	

Choose a	a submission ty	pe:*		Choose a Submission-Unit:*		
vptmf			•	No selection	-	]
2	Select releva	ant Subr	nission-	Unit		
Choose a	Submission-Un	it:*				
No selectio	on		•	]		
No sele	ction			)		
initial						
validati	on-response					
respons	se					
addition	nal-info					
closing						
consolio	dating					
corriger	ndum					
reforma	at					
3	The submiss	ion form	nat cann	ot be changed and must		
	always be 'V	NeeS'.				
4	Enter the vP	TMF nur	nber in	the correct format in the free	The n	umber must follow the
	text field. Th	e vPTM	= numbe	er will be communicated prior	forma	t: EMEA/V/VPTMF/xxxx
	to the start of	of the pi	ocedure	2.		
Submissio	on format:"	VNee9	3		*	
				,		
		Chicry	v/ vr mu /			
		Please EMEA	ensure /V/VPTM	the number adheres to the correc F/XXXX	ct format -	
5	vPTMF varia	ation			The nun	nber must follow the
5	Enter the vP	TMF pro	cedure r	number in the correct	format:	
	format in the	e free te	xt field.	The vPTMF-var procedure	EMEA/V	/VPTMF/XXXX/VRA/YYYY
	number will	be comr	nunicate	ed prior to the start of the	or	
	procedure.				EMEA/V	PTMF/XXXX/VNRA/YYYY
Submission format:			VNeeS		-	
VPTMF procedure number:* EMEA/			EMEA/V	/VPTMF/		
Please ensure the number adheres to the correct format -					ormat -	
EMEA/V/VPTMF/XXXX/VRA/YYYY or EMEA/V/VPTME/XXXX/VRA/YYYY/						
F	Add the MAI	lnomo		Distance in the free tout field	~	
Э	Add the MAR	name	anu the	riaciorin in the free text field	5	
MAH Name	e:* Enter	MAH Nam	e			
Platform	Enter	Platform				
6	Click 'Genera	ate deliv	ery file'	and save the delivery file on	The d	elivery file should not
	your comput	er			be an	nended or re-named.

### 12. Create delivery file screen – Paediatric submissions

PLEASE NOTE UPCOMING CHANGE FOR PAEDIATRIC SUBMISSIONS:

#### Paediatric submissions to launch on IRIS platform from 4 June 2024

Please note that from 4 June 2024, the paediatric submissions must be carried out via <u>IRIS</u>. For more information please see the <u>announcement</u>.

\_\_\_\_\_

More information can be found in the Guidance on Paediatric submissions.

For any questions on technical issues, please contact EMA ServiceNow.

For Paediatric submissions regarding procedures please contact <u>ASK EMA</u>.

Human		Veterina	ry		
Choose a submission type:*	Choose a Procedure Type:*		Choose a Submission-Unit:*		
paediatric submissions -	No selection	-	No selection	٠	
	*Denotes mandatory fields				
Submission: paediatric submissions					
Generate delive	ry file	Reset form			

#### 12.1. Create delivery file for Paediatric submission

#### Go to: Delivery file UI

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 submissions should not contain both annual report and responses to PDCO request for information       Paediatric submissions e.g. Paediatric Investigation Plan (PIP) submissions, waivers, deferrals and modifications.         Image: the type image: ty	Ste	ep	Description				Notes
Human Veterinary   Choose a submission type:* Choose a Procedure Type:* Choose a Submission-Unit:*   paediatric submissions Paediatric Investigation Plan No selection   *Denotes mandatory fields   Submission: paediatric submissions   2 Depending on the selected Procedure type and the submission unit, you may need to select a Submission		1	Select Submission typ proceed to select the relevant submission u only a single 'regulato submission should not responses to PDCO re	in	Paediatric submissions covers all types of paediatric submissions e.g. Paediatric Investigation Plan (PIP) submissions, waivers, deferrals and modifications.		
Choose a submission type:*       Choose a Procedure Type:*       Choose a Submission-Unit:*         paediatric submissions       •       Paediatric Investigation Plan       •       No selection       •         *Denotes mandatory fields       •       Denotes mandatory fields       •	Human				Veterinar	y	
paediatric submissions     *Denotes mandatory fields     Submission: paediatric submissions     2   Depending on the selected Procedure type and the submission unit, you may need to select a Submission		Choose a	submission type:*	Choose a Procedure Type:*		Choose	a Submission-Unit:*
*Denotes mandatory fields Submission: paediatric submissions 2 Depending on the selected Procedure type and the submission unit, you may need to select a Submission		paediatric	submissions •	Paediatric Investigation Plan	•	No sele	ction 🝷
Submission: paediatric submissions         2       Depending on the selected Procedure type and the submission unit, you may need to select a Submission	*Denotes mandatory fields						
2 Depending on the selected Procedure type and the submission unit, you may need to select a Submission	Submission: paediatric submissions						
description.		2					

Choose a Proce	edure Type:*	Choose a Submission-Unit:*	Choose a Submissi	on description:*
Paediatric Invest	igation Plan 👻	Notification of change 🔹	No selection	-
Active Su	*Denotes ma Submission: pac bstance (INN):*	ediatric submissions	No selection Applicant change Applicant partice Authorised conta Public enquiry co Response to Day Response to Day	e due to take-over by new legal entity ulars' change act person change ontact change y 30 PDCO discussion y 90 PDCO discussion
3	Enter the Procedu The procedure nu specific format. Y procedural docum	ire number. mber is an alphanumeric val ou can find this number from ients.	ue with a n all	The PIP number field has been renamed to Procedure number and a format for the number is enforced
Procedur Enter Prod	re number:* cedure Number	ediatric procedure number is be found on all procedural cuments (EMA decision, PDCO nion, Summary report) and mmunications sent to the olicant via EudraLink. It would ve one of the following mats: EA-xxxxxx EA-xxxxxx EA-xxxxxx-PIPxx-yy EA-xxxxxx-PIPxx-yy-Mxx EA-Cx-xxxxxx-PIPxx-yy-Mxx		
4	Enter the Active s Alternatively, you common name or	ubstance (INN). can enter the pharmacopoe exact scientific/chemical na	ia name, me.	More information can be found from the <u>Guidance on</u> <u>Paediatric submissions</u> .
Active S	SUDMISS Substance (INN):*	Recommended INN, EU Pharmacopoeia name, comm name or exact scientific/che name in this order of desce preference.	mon emical nding	
5	You are also invit optional field.	ed to provide the RPI in this	new	More information on the Research Product Identifier and how to obtain one can be found from the <u>IRIS website</u> .
RPI:	Research Product Ic iris.ema.europa.eu	entifier:		
6	For certain proceed contact persons e	dures you will be asked to pr mail address.	ovide the	This contact person will be contacted in case the notification cannot be processed.
Contact pers	son's email address:*	Please provide the email address of the person who is the responsible for this notification of change. This person will be the contacted of the Notification cannot be processed.		

For next steps refer to chapter "15. Saving the XML delivery file and preparing the submission package".

## **13.** 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.

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

Step	Description		Notes	
1	Select submission 'initial'. The mo	on type 'Signal Detectic de is always single.	on' and submission unit	
Choos	e a submission type:	Mode: * 👩		
signal	detection	▼ Single Product ▼		
2	The product typ Please enter the	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.		
	Subn			
Proc	luct Type: <sup>*</sup>			
Nat	ional 👻			
3	Enter the 5-digi sent by EMA.	The number consists of 5 numbers		
4	Search for the r product name in type the more t	It is possible to select more than one product name from the list to ensure that all		

x x x x	K MAH nam SANOFI BE SANOFI BE SANOFI BE	Select a RHINOSPRAY TRAMAZOLINE e e ELGIUM ELGIUM	Product (NAPs): Product full name Rhinospray Tramazoline Rhinospray Tramazoline	Enter produc 1,18 mg/ml 1,18 mg/ml 1,18 mg/ml	Country BE BE BE	Authorisation No BE128807 BE128807 BE128807	EV Code PRD5243799 PRD5243788 PRD5243823	EMEA Product/MRP/DCP	
*	K MAH nam SANOFI BE	Select : RHINOSPRAY TRAMAZOLINE e ELGIUM	Product (NAPs):* Product full name Rhinospray Tramazoline Rhinospray Tramazoline	Enter produc 1,18 mg/ml 1,18 mg/ml	Country BE BE	Authorisation No BE128807 BE128807	EV Code PRD5243799 PRD5243788	EMEA Product/MRP/DCP	
×	K MAH nam SANOFI BE	Select a	Product(NAPs):*	Enter produc	Country BE	Authorisation No BE128807	EV Code	EMEA Product/MRP/DCP	
*	K MAH nam	Select a	a Product(NAPs):*	Enter produc	country	Authorisation No	EV Code	♥ EMEA Product/MRP/DCP	
×	¢	Select a	a Product(NAPs): <sup>*</sup>	Enter produc	t short name			•	
		Select	a Product(NAPs):*	Enter produc	t short name				
Enter Epitt number: 12345									
	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.								
	6	You can select all p field next to 'MAH r lines to select relev	roducts/prese name' field. Al vant products/	ntations ternative presenta	by click ly, click tions.	king to the k individual	At least products be selec	one of the s/presentation must ted.	
	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.								
		The list of Nationally Authorised Products with retrieved from products (Art. 57 database).						cted.	
		The list of National	ly Authorised	Products	with re	trieved from	products	s and presentations	

## 14. Create delivery file screen – Article 18 submissions

The European Medicines Agency (EMA) may review COVID-19 vaccines and treatments under Article 18 of the Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123). This is intended to support national decision-making on the possible use of these medicines before a formal authorisation is issued.

The Art. 18 submissions should be submitted to the EMA via the eSubmission Gateway in eCTD format.

#### 14.1. Create delivery file for Article 18 submission

your computer.

1       Select submission type 'Signal Detection' and relevanat         submission unit. For example, for the first submission the         submission unit is 'initial'. The mode is always single and the         submission format is defaulted to eCTD.         Please enter the eCTD sequence number.	Step	Description	Notes
product.	1	Select submission type 'Signal Detection' and relevanat submission unit. For example, for the first submission the submission unit is 'initial'. The mode is always single and the submission format is defaulted to eCTD. Please enter the eCTD sequence number.	The sequence number should be the next number is the eCTD lifecycle of the product.

		Human		Veterir	hary	
	Submission Type* article-18	▼ St	ubmission-Unit* nitial	•	Mode*  Single Product	
			*Denotes ma	ndatory fields		
		Submission format* eCTD	ubmission •	: article-18 Sequence number* 0000		
2	<ul> <li>2 Please enter <ul> <li>The Company/Applicant name</li> <li>Substance name</li> <li>Contact person name, email and telephone number</li> <li>in the mandatory free text fields.</li> </ul> </li> </ul>					
3	3 Click 'Generate delivery file' and save the delivery file on The delivery file should not be amended or re-named.					

# **15.** Saving the XML delivery file and preparing the submission package

Step	Description	Notes				
1	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					
Do you want to	o open or save <b>delivery_659819671.xml</b> (527 bytes) from <b>esubweb.ema.europa.eu</b> ?	Open Save 🔻 Cancel 🗙				
Opening delivery_829 You have chosen to delivery_829; which is: XML from: https:// What should Firefo Open with Save File Do this auto	784281.xml open: <b>F84281.xml</b> Document (529 bytes) esubweb.ema.europa.eu x do with this file?  Office XML Handler (default)  matically for files like this from now on.  OK Cancel					
<ul> <li>Save the delivery file in a location where you can easily find and identify it (especially if you are creating multiple delivery files).</li> <li>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.</li> </ul>						
3	The delivery file should be saved in the <b>top-level folder</b> of the submission package.	Ensure your VNeeS root is placed in a higher-level folder				

It is important to name the submission zip package with the 4-digit sequence number. If your submission is not in eCTD, please use 0000. The sequence number in the delivery file and inside the submission package must be the



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

Computer ► pu Organize ▼ New folder Favorites Desktop Downloads Recent Places	Name Mame delivery_829784281	Save the delivery file in the same folder with the submission folder Date mounted 19/05/2016 19:12 19/05/2016 19:13	Type File folder XML Document	
Documents	Date modified Type	Size		
0000	19/05/2016 19:12 File folder		Zin the submission	
(***) delivery_829784281	7-Zip     *       %     Combine files in Acrobat       2     Edit with Notepad++       3     Scan for threats       Always available offline       Send to	1 1KB 2	folder and the delivery file together	



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

(				
🔾 🗢 📗 « kaczmarczykd (	\\FSb\eudralink) (L:) 🕨 \	/etproduct IB 0015 🕨 🔶	• •	Save the delivery file in the same folder with the submission folder
Organize 🔻 New folder			vel folder (ZIP)	
		Nama		-
Contraction (Contraction)		Name		
		퉬 root-vetproduct-em	ea-v-c-035-IB-0015	
Documents		delivery_1066022769	· A	
Music			າເ	
Pictures		,	/NeeS root folder	
Videos 🗧			incestoot fonder	
🖳 Computer				
🖵 emea (\\FSa) (G:)				
nk) (L) > vivees >			• • • • • • • •	
Name	Date modified	Type Size		
Proct-vetraill-v-c-002010-ib-005-may2016	20/05/2016 08-19	Eile folder	Zip the si folder and	ubmission d the
delivery_769537063		a Demonst 1 K	delivery f	ile together
(	7-Zip		·	
	🐁 Combine files in Acr	obat		
	Edit with Notepad++	+) (	1	
	Scan for threats			
	Always available offl	ine	2	
	Send to	Compressed (	zipped) folder	
🔾 🗢 📕 🕨 Computer 🕨 puusaari (\\FSb\eudralii	nk) (L:) 🕨 VNeeS 🕨			
Organize   New folder				
🔶 Favorites	Name	Date modified	Type Size	
Desktop	🖾 VC0001234 Vetpill	20/05/2016 09:16	zip Archive 1	l,718 KB
Downloads	*			
🗐 Recent Places				
			Once you have create zip folder you may ch folder only contains th submission root folder delivery file. Send this zip package eSubmission Gateway/eSubmissior Web Client	d the single eck that the ne r and the using n Syncplicity
EMA/346582/2016				

Zz L:\	VNeeS\	VC00012	34 Vetpil	l.zip\				
File	Edit \	/iew Fa	avorites	Tools	Help			
4		$\checkmark$	u	-	×	ភី		
Add	Extrac	t Test	Сору	Move	Delete	Info	_	
ø	💶 L:\V	NeeS\V(	0001234	Vetpill.	zip\	_		
Nam	e							
iroot-vetpill-v-c-002010-ib-005-may2016 delivery_769537063.xml								

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

Organize ▼ 1 Open ▼ New folder	Save the of file in the folder with submissio	delivery same n the n folder				
r ★ Favorites ■ Desktop	Name	Name		Date modified Type Si 20/05/2016 08:58 File folder		
Downloads Recent Places	(interpersion) [interpersion] [inter	(≝) delivery_658647866			ML Document	
Organize 👻 🚔 Open New folder	) (L:) + PIP + 001968 paediatrics +					
<ul> <li>★ Favorites</li> <li>■ Desktop</li> <li>▶ Downloads</li> <li>™ Recent Places</li> <li>₩ Libraries</li> <li>▶ Documents</li> <li>▶ Music</li> <li>➡ New Library</li> <li>➡ Pictures</li> <li>■ Videos</li> </ul>	Name 2016-may-pip-001968 delivery_658647866 1	Date modifie       20/05/2016 0  <	d Type 8:58 File fold 9:00 XML Do + ccrobat ++	er cument 2	Zip the submission folder and the delivery file together	
Computer > puusaari (\\FSb\eudra	alink) (L:) 🕨 PIP					
Favorites	Name D 2 001968 Paediatrics 2		Date modified T Gat 20/05/2016 09:07 z		Send the zip using eSubmission Gateway/eSubmission Syncplicity Web Client	

**Example**: Place the XML delivery file in other **non-structured** submissions for example Raw Data submission

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, for example for Raw data submissions you can use the product name or the product number. 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 <b>failure of the submission</b> .	Note: It is important that only 1 delivery file is included in the submission package. It is important that the delivery file is not inside the submission content zip file.
5	Log into eSubmission Gateway or the <u>eSubmission</u> <u>Syncplicity Web Client</u> and send the package following instructions in the user guide.	See user guide ' <u>How to send</u> submissions via the Syncplicity <u>Web Client</u> '
eu.syncplicity.com		
	syncplicity by axway	

The easiest way to sync and share your files Log in to Syncplicity

Email	
Password	
	Log in

Create Account Reset Password Where do I enter my password?

### **16.** 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/eSubmission Syncplicity Web Client, please contact the EMA via the <u>EMA ServiceNow</u>.