



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Validation checklist for initial MAA under Regulation (EU) 2019/6 – pharmaceuticals

1. Background on the product

(Invented) Name and procedure number:

INN or common name:

Indication applied for:

This validation checklist is used by the Agency to validate initial marketing authorisation applications for pharmaceuticals and applicants should use it as a means to review in advance of their submission that standard requirements are fulfilled.

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For the below table, please fill out by referring to the application form one line for each presentation per strength and form. Check consistency with the SPC. This is aimed at having the correct count for the fees.

Strength (2.2.1 in AF)	Pharmaceutical Form (2.2.1 in AF)	Target species (2.1.4. in AF)	Route of administration (2.2.2. in AF)	Immediate Packaging (2.2.3 in AF)	Content (concentration) (2.2.1 in AF)	Package size (2.2.3 in AF)
As declared in the SPC, section 2; e.g. 25 mg; 100 IU/ml [Qualitative and quantitative composition of the active substance or substances and qualitative composition of excipients and other constituents (e.g. adjuvants) stating their common name or their chemical description and their quantitative composition, if that information is essential for proper administration of the veterinary medicinal product. Expressed per dosage unit or according to the form of administration for a given volume or weight. E.g. for vaccines: "Each 2 ml dose contains {x} units {active substance}"]	The pharmaceutical form is expressed in accordance with standard terms of the EDQM (user name and password needed, request them from the library/information centre) Singular only				Only for liquids, creams and solid multidose forms, e.g. 5 ml only	Quantitative information Specify the pharmaceutical form in a simplified way (eg 1 vial, 60 capsules)

2. Summary of Flags to PM (For internal use only)

3. Background documentation:

Topic	Document
User guide for the electronic application form for a marketing authorisation (veterinary)	http://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Procedural_guidance/General_info_on_applications/eSubmission/User_Guide_for_the_electronic_application_form_for_a_marketing_version_3.pdf
Commission Delegated Regulation (EU) 2021/805	Publications Office (europa.eu)
EDQM database of TSE/chemical certificates (CEPs)	https://extranet.edqm.eu/publications/recherches_CEP.shtml
Glossary of terms	Glossary European Medicines Agency (europa.eu)
Veterinary e-submission guidelines	http://esubmission.ema.europa.eu/tiges/vetesub.htm
Link to the European Pharmacopoeia	http://online.phEur.org/EN/entry.htm
Guideline on Active Substance Master File Procedure	<p>Active substance master file procedure European Medicines Agency (europa.eu)</p> <p>GL on ASMF assessment worksharing procedure and HMA Q&A on ASMF: Heads of Medicines Agencies: Working Group on Active Substance Master File Procedures (hma.eu)</p> <p>EMA Q&A on ASMF: Pre-authorisation guidance under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6) European Medicines Agency (europa.eu)</p>

Topic	Document
<p>COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin</p>	<p>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0037&from=EN</p>
<p>ATCvet codes</p>	<p>https://www.whocc.no/atcvet/atcvet_index/</p>
<p>EDQM standard terms: (It is used to check the dosage form (=pharmaceutical form) and route of administration.)</p>	<p>https://standardterms.edqm.eu/</p>
<p>Process for handling new standard term requests received from applicants in the pre-submission phase (or from other sources, also during any procedure):</p>	<p>If a new term (e.g. pharmaceutical form or unit of measurement) or a request for an update of an already existing term is needed in order to complete the eAF, a request should be submitted through the SPOR Portal - http://spor.ema.europa.eu/rmswi/#/ providing as much supporting documentation as possible (e.g. name of the product concerned, SPC, etc).</p>
<p>EUTCT: to check the target species</p>	<p>http://eutct.ema.europa.eu/eutct/showAvailableListsDisplay.do?guestuser=true</p>
<p>Fees guidance published on EMA website (document to be updated yearly)</p>	<p>Fees payable to the European Medicines Agency European Medicines Agency (europa.eu)</p>
<p>Ph. Eur.: if the applicant declares that the reference for a substance (active substance or excipient) is the Ph. Eur. , there is a need to check that they use the name in the Ph. Eur and not any other equivalent name.</p>	
<p>ASMF templates for letter of access (Annex 2) and submission letter (Annex 3 of ASMF GL):</p>	<p>Active substance master file procedure European Medicines Agency (europa.eu)</p>
<p>Policy describing administrative issues blocking a positive validation of Marketing Authorisation Applications and I VRAs</p>	<p>EMA/233682/2022 https://docs.eudra.org/webtop/drl/objectId/090142b2852e582d</p>
<p>EMA internal guidance - Brexit – Impact for EMA of the end of the transition period and the EU-UK Trade and Cooperation Agreement</p>	<p>EMA/819960/2022 https://docs.eudra.org/webtop/drl/objectId/090142b284df86a5</p>

4. Checklist

Definitions:

VSI: Validation Supplementary Information. Information that will be requested by the Agency to the applicant during the validation period and that should be resolved before the start of the procedure, if not indicated otherwise. Please note that the deficiencies should be addressed not later than 2 months from the initial submission date. If no or unsatisfactory responses are received within 2 months, the validation outcome will be considered negative and the application closed. An invoice for the relevant administrative fee will follow.

Blocking issue: An issue that has been identified during the validation period and that should be resolved before the start of the procedure, otherwise it would prevent validation of the application.

General Application Form checks		
Is the information on product name, active substance, strength(s) and pharmaceutical form(s) given consistently (and correct) between cover page of the application form, sections 2.1.1, 2.1.2 and 2.2.1 of the application form and Product Information (PI)?	Select	<i>If No, request corrected application form and/or PI, as appropriate.</i>
Confirm Product Shared Mailbox, SIAMED, EURS, DREAM Product Folder are consistent with the Product Name given in the Application Form	Select	<i>Immediately contact vet applications/ VO and ask for these to be amended. Product Shared Mailboxes are created by eligibility team.</i>
Are all Annexes as ticked in section '5- Annexed documents' provided?	Select	<i>Double check with boxes ticked in the individual sections, too. If an Annex is missing issue VSI</i>
Are the names and address of the Manufacturer(s) of the Finished product and of the Active substance(s) correct in the eAF and SIAMED?	Select	
Is the product classified as novel therapy? If yes, is a Risk Management Plan present?	Select Select	<i>When a product is a novel therapy, this is stated in the eligibility letter. Check with SL in doubt, and if the product is a novel therapy, and the Risk Management Plan is not present, the procedure</i>

		cannot be validated.
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Part 1a: Application Form		
<i>Please ensure that all details given in the application form on product and applicant (incl. address) are consistent throughout the document</i>		
GENERAL CONSIDERATIONS		
<p>Has correct version of Application Form been used?</p>	Select	<p><i>Use of the correct e-application form is mandatory. Check first page of application form against the latest version.</i></p> <p><i>If not, request relevant missing/changed parts. The applicant can provide the correct version of the eAF within responses to validation issues plus missing documents.</i></p> <p><i>If missing information is not provided by the validation date, suspend the validation.</i></p> <p><i>The last opportunity for the applicant to submit a revised dossier and resolve validation issues will be 2 months from the initial submission date. If the revised dossier is not submitted within this time limit the Agency will consider the application withdrawn in accordance with Article 6(6) of Regulation (EU) 2019/6.</i></p>
<p>Product (Invented) Name:</p> <p>Has submitted name been agreed with the CVMP/Invented Name Check?</p> <p>Is the name the same as indicated in section 2.1.1 and in the Product</p>	Select Select	<p><i>The invented name should be agreed by CVMP prior submission. However, this is not a validation issue if name not agreed yet.</i></p>

Part 1a: Application Form

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GENERAL CONSIDERATIONS

information.		<p><i>Note: although it is recommended that the invented name is written with the first letter in upper case and the rest as lower cases, it is ultimately the choice of the applicant (either upper or lower case), as long as it is written in a consistent format throughout the PI and is consistent with how the invented name will appear on the printed artwork.</i></p> <p><i>Reference: Compilation of QRD Decisions on stylistic matters - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/compilation-quality-review-documents-decisions-stylistic-matters-product-information_en.pdf</i></p>
Cover letter:	Select	
Cover letter: Is the person authorised to communicate on behalf of the applicant the same as indicated in section 2.4.2 of the application form and is a letter of authorisation attached for this person (Annex 5.4)?	Select	<p><i>If not, or letter not provided/not correct, request corrected application form/letter.</i></p>
Cover letter: Is signatory on behalf of the applicant either CEO of company, member of management board etc. or a person authorised to communicate on behalf of the applicant, i.e. the designated person as indicated above?	Select	<p><i>In case person is different from above ('person authorised to communicate on behalf'.</i></p>

Part 1a: Application Form		
<i>Please ensure that all details given in the application form on product and applicant (incl. address) are consistent throughout the document</i>		
1.1 Eligibility ticked as agreed by CVMP and date correct?	Select	
1.3 Legal basis:	Select	<i>Check correctness with Letter of Intent (CVMP response to the applicant) and eAF.</i>
1.3.5 Article 21 - Informed consent application <ul style="list-style-type: none"> • The scope of the application is the same as the reference product. • If informed consent is ticked as the legal basis for the application, information on the reference medicinal product is given below (Product invented name, pharmaceutical form(s), strength(s), Marketing authorisation holder, MA Number(s) and Date of authorisation). • Annex 5.2 is ticked in the eAF and the letter of consent from marketing authorisation holder of the authorised (parent) product is attached in Part 1a. • Complete administrative data is provided in the application (including SPC). 	Select Select Select Select Select	<i>If informed consent is not ticked as the legal basis, select N/A. Only a complete administrative data must be provided in the application, with consent to use the pharmaceutical, safety, (pre-clinical) and clinical data of the reference product given by the parent MA holder. In this case, there is no need to submit quality, safety and efficacy detailed and critical summaries. If the parent product belongs to the same MAH (so called "self-informed" consent), the letter of consent must still be provided - it is not correct when the applicant justifies that this is not applicable.</i>

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		<p><i>E.g. if target species is dairy cattle, an MRL for milk is applicable; if target species is laying hens, an MRL for eggs is applicable.</i></p>
<p>1.5 Additional requests for consideration: Has the applicant provided documents in support of his request for</p> <p>1.5.1. Accelerated assessment procedure</p> <p>1.5.2 Prolongation of data protection: Article 40(1) of Regulation (EU) 2019/6 (where the first MA is granted for >1 species referred to in point (a) or (b) of Article 39(1), or a variation is approved in accordance with Article 67 which adds another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by one year for each additional target species, provided that, in the case of a variation, the application has been submitted at least three years before expiration of the protection period laid down in point (a) or (b) of Article 39(1))</p> <p>1.5.3 Prolongation of data protection: Article 40(2) of Regulation (EU) 2019/6 (where the first MA is granted for >1 species referred to in point (d) of Article 39(1), or a variation is approved in accordance with Article 67 which adds another species not referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by four years, provided that, in the case of a variation, the application has</p>	<p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p>	<p><i>1.5.1 In case the applicant ticked accelerated assessment, check in SIAMED that this info has been recorded. Accelerated assessment procedure should be assessed during the eligibility stage so a correct timetable is agreed. If not ticked, select 'N/a'. If granted, flag to S/CL and indicate in SIAMED for the correct TT. If box ticked but accelerated review not approved indicated in SIAMED, check with SL, issue VSI and immediately flag issue to S/CL.</i></p> <p><i>If yes, flag it up to Vet Regulatory Affairs</i></p> <p><i>If yes, flag it up to Vet Regulatory Affairs</i></p>

Part 1a: Application Form

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		are stated: ectoparasitocides for topical use incl. insecticides, sulphur-containing products. If an ATC vet code is published by the WHO, but it is not used in the application, a justification should be provided. If an ATC vet code has not yet been assigned, the eAF and the PI should be left blank.
2.1.4 Target species	Select	Should be in line with product information. If a new target species or a request for an update is needed in order to complete the eAF, a request should be submitted through the SPOR Portal - http://spor.ema.europa.eu/rmswi/#/ providing as much supporting documentation as possible (e.g. name of the product concerned, SPC, etc).
2.1.5 Withdrawal period (only for food-producing species)	Select	
2.2.2 Route of administration: In line with Standard Terms?	Select	Check against standard terms (EDQM). If a new term (e.g. pharmaceutical form or unit of measurement) or a request for an update of an already existing term is needed in order to complete the eAF, a request should be submitted through the SPOR Portal - http://spor.ema.europa.eu/rmswi/#/ providing as much supporting documentation as possible (e.g. name of the product concerned, SPC, etc).
2.2.3 Container, closure and administration device(s) Are information provided in line with Part 2 and Product Information?	Select	The container should be selected from the List of Standard Terms published by the EDQM. .

Part 1a: Application Form

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	Select	
2.5.1.1 Has a person responsible for product defects and recalls in the EEA been named along with contact details? (should include at least name / surname, address with postcode and country, 24H tel. # and e-mail address)	Select	<i>Person has to be located in the EEA.</i>
2.5.2 Proposed Manufacture of the Finished Product (FP): Is the name and address of the Manufacturer of the FP the same as in Annex 5.8	Select	<i>Details of the name and the address mentioned in Annex 5.8 to be checked that are as in point 2.5.2 (2.5.1) in the eAF.</i>
2.5.3 Proposed Manufacturer of the active substance: Is the name and address of the Manufacturer of the Active substance (s) exactly the same as in the Active substance master file (ASMF) or Ph. Eur. Certificate (CEP), as applicable.	Select	<i>Annex 5.6, 5.9 have to be provided (Checked by inspections). Details of the name and the address mentioned in the ASMF/CEP to be checked that are the same as in point 2.5.3 of the eAF.</i>
2.5.3 Ph. Eur. Certificate for the active substance(s) (CEP): If a certificate is claimed to have been issued, has a valid, up-to-date copy been provided in Annex 5.10?	Select	<i>Check the EDQM certificate database online at https://extranet.edqm.eu/publications/recherches_CEP.shtml N.B.: If nothing is ticked, it means that it is not applicable. If Yes is ticked and there is no certificate, then it's a VSI Details on CEP-related requirements - please see below in the CEP section at the end of part 2.</i>
2.5.3 Ph. Eur. Certificate (CEP): If a CEP is used, are the following clearly identified: <ul style="list-style-type: none"> • Name of the CEP holder • Name of the manufacturer • CEP number • Date of last update 	Select	<i>Check the EDQM certificate database online at https://extranet.edqm.eu/publications/recherches_CEP.shtml N.B.: If nothing is ticked, it means that it is not applicable. If Yes is ticked and there is no certificate = VSI Check that the CEP and application form are consistent regarding each of the bullet points opposite Details on CEP-related requirements - please see below in the CEP section at the end of part 2.</i>
2.5.3 Active substance master file (ASMF):	Select	<i>- If the ASMF is not used, select N/A and leave the ASMF-related boxes below blank - If presence of the ASMF is indicated in the AF, check if the ASMF from the ASMF holder was</i>

Part 1a: Application Form

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		<p><i>provided</i></p> <ul style="list-style-type: none"> - If ASMF is missing (not submitted) = blocking issue - If ASMF is indicated and was submitted by the ASFM holder, proceed with the following checks of the application form section 2.5.3 and check of the ASMF itself
<p>If an ASMF is used, are the following clearly identified in the AF:</p> <ul style="list-style-type: none"> • Name and address of ASMF holder • Name of manufacturer if different from above • EU ASMF reference number or National (EMEA) ASMF reference number as applicable • Applicant's part version number ASMF submission date and date of last update • The letter of access provided by the ASMF holder to the Applicant should follow the format of Annex 2 of the Guideline on Active Substance Master File Procedure (EMEA/CVMP/134/02) and should be provided in Annex 5.10 of the AF. • Confirmation that changes will be notified (Annex 5.11 provided). It is part of the access letter (Annex 5.10) if the ASMF Guideline template is used. • The ASMF and application form are consistent regarding each of the bullet points above (check Submission Letter and Administrative Details in the ASMF) 	<p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p> <p>Select</p>	<p><i>Name of manufacturer if different from above: Make sure the signature on the letter of access is correct (i.e. if the manufacturer signs ON BEHALF of the ASMF holder, this needs to be appropriately authorised</i></p> <p><i>Please note that :</i></p> <ul style="list-style-type: none"> - <u>EU ASMF number</u>: is in place from December 2013. This number is to be allocated if the ASMF assessment worksharing procedure is used. The EU/ASMF/XXXXX will be allocated by submissionregistration@ema.europa.eu (or an NCA, in case of an earlier submission of the ASMF in a national MAA/MAV) upon request by the ASMF Holder, before ASMF submission. The request of the EU ASMF number is not mandatory, but it is mandatory to have EITHER the EU or the National (EMEA) ASMF number. - <u>National (EMEA) ASMF number</u>: is in place from 1st September 2013. It is the EMEA number the Agency will allocate to ASMF submitted only centrally and the ASMF assessment worksharing procedure is not used for that ASMF. The EMEA/ASMF/XXXXX will be allocated by submissionregistration@ema.europa.eu upon requested by the ASMF holder, before ASMF submission. An ASMF should always be submitted with one of the two (EU or EMEA) numbers.

Part 1a: Application Form

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		<p><i>Have the letter of access and letter with confirmation regarding notification of any changes been provided (note: can be combined into 1 letter - template of Annex 2)</i></p> <p><i>In the ASMF holder submission: Submission Letter and Administrative Details in the ASMF (Annex 3 template): check that the 4 pages of the template have been completed. Many times the ASMF holder deletes the 4th page and it always has to be submitted.</i></p>
<p>Further explanations for the validation of the ASMF are below in the checklist at the end of part 2.</p>		
<p>2.6.1 Qualitative and Quantitative composition: Is the information in this section in agreement with the relevant information in Part 2, 2a-qual-quant-partic?</p>	<p align="center">Select</p>	<p><i>For liquids, not only concentration per 1 ml needs to be given but also the container size/volume of the product. This can be found either in the AF point 2.2.3 (or 2.2.3.1) or 2.6.1.</i></p> <p><i>If VSI - Pharmacopoeia terminology should be used.</i></p> <p><i>This excludes components that are not present in the final dosage form.</i></p> <p><i>There is no information that can be withheld as confidential in providing a regulatory submission to the Agency. E.g. composition of tablet coating mixtures.</i></p>
<p>2.6.1 Qualitative and Quantitative composition: Cross-check with Part 2, 2a-qual-quant-partic Active substance Overages</p>	<p align="center">Select</p>	<p><i>Notes:</i></p> <ul style="list-style-type: none"> <i>- Complete composition to be provided; no information can be confidential - all to be disclosed to the Agency. E.g. for commercially available tablet film-coating mixtures <u>quantitative</u> composition needs to be provided (through confidentiality agreement between the applicant and the mixture manufacturer).</i> <i>- For liquids, not only concentration per 1 ml needs to be given but also the container</i>

Part 1a: Application Form

Please ensure that all details given in the application form on product and applicant (incl. address) are consistent throughout the document

		<p>size/volume of the product.</p> <ul style="list-style-type: none"> - Reference to Ph. Eur. for excipients is preferable. If reference to USP/NF or JP is used instead, VSI (but not a blocking issue if not provided with the responses) - Overages - extra amount of the active substance or excipients added to compensate for losses during manufacture/storage. Generally discouraged - Overfill should not be stated in the Application Form - if it is = to be removed.
<p>2.6.2 Materials of animal origin Cross-check with Part 2, 2c4-bio-origin.</p>	<p align="center">Select</p>	<p>All material of animal origin should be stated including reagents in the active substance manufacture.</p>
<p>2.6.2 TSE certificate: If applicant has ticked and given the number of a Ph. Eur. Certificate of suitability, is it/are they duly annexed in 5.12?</p>	<p align="center">Select</p>	<p>Information on excipients to be consistent with Part 2, 2c4-bio-origin (TSE table A and table B). TSE tables applicable only for materials of animal origin</p> <p>In EDQM database, it is better to search for the Certificate number (Certificate of suitability for TSE)</p> <p>Check the EDQM certificate database online at https://extranet.edqm.eu/publications/recherches/CEP.shtml</p> <p>Lactose is out of the scope of TSE requirements, as TSE transmission was never confirmed through milk. If Lactose is contained in the product, it never has a Certificate, only statement from the manufacturer (appendix to AF 5.12) that it is sourced in the same way as milk for human consumption. However, the option "animal origin susceptible to TSE" still needs to be ticked in the Application Form.</p>
<p>4.1 Other MAA (for national applications only)</p>	<p align="center">Select</p>	<p>In case of Art 42(4) the point is applicable for CAPs. Check if something has been ticked and the corresponding fields have been filled in, and if applicable, Annex 5.15 has been provided.</p>

Part 1 – excluding application form

1b SPC, Labelling and Package Leaflet:

Are they provided in EN for all of the applied for forms/strengths?

Select

Is Word version of the PI provided (in folder 'add-info')?

Select

Is the correct (QRD) format (latest version) used for the product literature?

Select

If combined PL, is the justification present?

Select

Note: If Word version not provided, not a VSI but necessary to be received by day 1 of the procedure.

Dossier- structure

<p>All documentation should be submitted using file formats that facilitate reviews on screen</p>	<p>Select</p>	<p><i>To allow functionality such as text searching, copying and pasting into editable formats, PDF documents should be created (rendered) directly from their electronic source documents. If scan of the document provided, it is recommended that they are searchable.</i></p>
<p>Structure of the folders</p>	<p>Select</p>	<p><i>Where the structure defined in Table 1 to Table 11 applies, including additional folders within the structure of the e-submission is not permitted, with the exception of the folder "add-info" where subfolders could be constructed. If there are empty folders in the submission because no data is provided these should be deleted as the folder structure should reflect only what actually is submitted. Corresponding positions in the relevant table of contents (TOC) should also be deleted.</i></p> <p><i>When only little information is presented for a number of folders at the same level of granularity, it is acceptable to include all the information in a single PDF at the higher level of the granularity. This should be indicated in the TOC.</i></p>
<p>Files naming</p>	<p>Select</p>	<p><i>The name of the files should be in English. They should be descriptive and unambiguous especially if more than one PDF is included in a particular section. Any information that may help identify the contents of the file is encouraged to be included in the file name.</i></p>
	<p>Select</p>	<p><i>Preferably the file name should include the part of the dossier where the document is located. In these cases file names should be based on the naming convention for dossier parts used in the folder structure as defined in Table 1 to Table 11.</i></p>

Part 1c – Critical expert reports

For new applications, statements justifying absence of data or specific parts/sections should be provided in the relevant detailed and critical summary. In case any of these docs need updating, updated expert signatures in Part 1c have to also be provided or updated docs have to be signed.

For each report a signature of the expert with date, a CV and a declaration of the professional relationship is necessary. Expert does not need to reside within the EEA. If it is obvious from the CV of the expert that he/she is an employee of the applicant, the declaration of his/her professional relationship can be omitted.

<p>1c1 critical expert report- Quality:</p> <ul style="list-style-type: none"> • Has the report been provided, together with: • CV of the expert • Declaration of his/her professional relationship to the applicant? • 	<p>Select Select Select</p>	<p><i>If the quality part is submitted in CTD format what the applicant has to submit is the quality overall summary and the CV of the expert. It can be here in part 1c1 or within Module 2 of the CTD.</i></p>
<p>1c2 critical expert report- Safety and Residues:</p> <ul style="list-style-type: none"> • Has the report been provided, together with: • CV of the expert • Declaration of his/her professional relationship to the applicant? • Tabulated summary of all technical documentation and relevant data submitted 	<p>Select Select Select Select</p>	<p><i>Separate reports might be provided for safety, residues (not required for non-food producing species) and ERA. Short check if the headings of the main subsections (pharmacology, user safety, ERA and residues (for food-producing species only) are present.</i></p>
<p>1c3 critical expert report- Efficacy:</p> <ul style="list-style-type: none"> • Has the report been provided, together with: • CV of the expert • Declaration of his/her professional relationship to the applicant? • Tabulated summary of all technical documentation and relevant data submitted 	<p>Select Select Select Select</p>	<p><i>Short check if headings of the main subsections are present (pre-clinical, including target animal safety and clinical)</i></p>

PART 2 (Quality)

The following formats for Part 2 (quality) are accepted for veterinary MAA pharmaceutical:

Option 1: According to Annex to Commission Delegated Regulation (EU) 2021/805 folder structure: electronic (VNeES)

Part 2 – Quality documentation (<i>physicochemical, biological or microbiological information</i>)		
<i>Check for either documents in the appropriate indent or a justification for absence has been provided in the quality overview -> If neither is present => VSI.</i>		
<i>The purpose of Part 2 validation is to check presence or absence of documents, not to read them.</i>		
Part 2 ToC	Select	<i>Should be in P2 folder but outside any of the subfolders within P2. (this is also checked by the VNeES checker)</i>
2.A Product description		
2.A.1 Qualitative and quantitative composition	Select	<i>It is acceptable not to create one folder per subsection (i.e. 2a1, 2a2) It can be all included in the same document. The information in this section should be consistent with section 2.6.1 of the application form.</i>
2.A.2. Product development	Select	
2.B. Description of the manufacturing method	Select	
2.C. Production and control of starting materials		
2.C.1 Active substance(s)	Select	
2.C.2. Excipients	Select	
2.C.3. Packaging (Container-closure system)	Select	
2.C.3.1 Active substance	Select	
2.C.3.2 Finished Product	Select	
2.C.4. Substances of biological origin	Select	<i>Tables A, B and C to be included here, if applicable. If there are no substances of animal origin the tables do not need to be included. The</i>

Part 2 – Quality documentation (physicochemical, biological or microbiological information)

Check for either documents in the appropriate indent or a justification for absence has been provided in the quality overview -> If neither is present => VSI.

The purpose of Part 2 validation is to check presence or absence of documents, not to read them.

		<i>information here should be consistent with section 2.6.2 of the application form.</i>
2.D. Control tests carried out at intermediate stages of the manufacturing process	Select	
2.E. Control tests on the finished product	Select	<i>All these subsections can be included in one pdf only and then maybe some annexes containing eg the results of batch testing (ie batch-to-batch consistency), validation of analytical methods, etc.</i>
2.E.1 General characteristics of the finished product	Select	
2.E.2 Identification and assay of active substance(s)	Select	
2.E.3 Identification and assay of excipient components	Select	
2.E.4 Microbiological controls	Select	
2.E.3 Batch-to-batch consistency	Select	
2.E.6 Other controls	Select	<i>2.E.6 Can contain information of any other test considered necessary to confirm the quality of the medicinal product. Not always applicable, if there is no information don't raise VSI.</i>
2.F. Stability test	Select	
2.F.1. Active substance(s)	Select	
2.F.2. Finished product	Select	
2.G. Other information	Select	<i>Can contain information related to the quality of the veterinary medicinal product but not covered in the previous sections. Not always applicable, if there is no information don't raise VSI.</i>

Option 2: According to Common Technical document (CTD) structure

Part 2 – Quality		
<i>Check for either documents in the appropriate indent or a justification for absence has been provided in the quality overview -> If neither is present => VSI.</i>		
<i>The purpose of Part 2 validation is to check presence or absence of documents.</i>		
3.2.S Drug Substance		
3.2.S.1 General Information		
3.2.S.1.1 Nomenclature	Select	
3.2.S.1.2 Structure	Select	
3.2.S.1.3 General properties	Select	
3.2.S.2 Manufacture		
3.2.S.2.1 Manufacturer(s)	Select	
3.2.S.2.2 Description of manufacturing process and process controls	Select	
3.2.S.2.3 Control of materials	Select	
3.2.S.2.4 Controls of critical steps and intermediates	Select	
3.2.S.2.5 Process validation and/or evaluation	Select	<i>For chemicals (ie pharmaceuticals, non-biologicals), process validation is only applicable to sterile active substances; otherwise N/A.</i>
3.2.S.2.6 Manufacturing process development	Select	
3.2.S.3 Characterisation		
3.2.S.3.1 Elucidation of structure and other characteristics	Select	
3.2.S.3.2 Impurities	Select	
3.2.S.4 Control of drug substance		
3.2.S.4.1 Specification	Select	
3.2.S.4.2 Analytical procedures	Select	<i>In 3.2.S.4.2 and 3.2.S.4.3 - for pharmacopoeial methods, reference to Ph.Eur. is sufficient.</i>
3.2.S.4.3 Validation of analytical procedures	Select	<i>Full validation reports of all methods (excluding Ph.Eur. methods) should be provided. Validation</i>

Part 2 – Quality

*Check for either documents in the appropriate indent or a justification for absence has been provided in the quality overview -> If neither is present => **VSI**.*

The purpose of Part 2 validation is to check presence or absence of documents.

		<i>summary is not sufficient.</i>
3.2.S.4.4 Batch analyses	Select	
3.2.S.4.5 Justification of specification	Select	
3.2.S.5 Reference Standards or Materials	Select	<i>Includes batch results/analysis (table) or certificate of analysis for the reference standard batch</i>
3.2.S.6 Container Closure System	Select	
3.2.S.7 Stability		
3.2.S.7.1 Stability Summary and Conclusions	Select	
3.2.S.7.2 Post-approval stability protocol	Select	
3.2.S.7.3 Stability data	Select	
3.2.P Drug product		
3.2.P.1 Description and composition of the drug product		<i>Should be consistent with section 2.6.1 of the Application Form.</i>
3.2.P.2 Pharmaceutical Development	Select	<i>Note: it is possible that no subfolders for the sections below can be found. It might be all in one document.</i>
3.2.P.2.1 Components of the drug product	Select	
3.2.P.2.1.1 Drug substance	Select	
3.2.P.2.1.2 Excipients	Select	
3.2.P.2.2 Drug product	Select	
3.2.P.2.2.1 Formulation developments	Select	
3.2.P.2.2.2 Overages	Select	
3.2.P.2.2.3 Physicochemical & biological properties	Select	
3.2.P.2.3 Manufacturing process development	Select	

Part 2 – Quality

*Check for either documents in the appropriate indent or a justification for absence has been provided in the quality overview -> If neither is present => **VSI**.*

The purpose of Part 2 validation is to check presence or absence of documents.

3.2.P.2.4 Container closure system	Select	
3.2.P.2.5 Microbiological attributes	Select	
3.2.P.2.6 Compatibility	Select	
3.2.P.3 Manufacture		
3.2.P.3.1 Manufacturer(s)	Select	
3.2.P.3.2 Batch formula	Select	
3.2.P.3.3 Description of Manufacturing Process and Process Controls	Select	
3.2.P.3.4 Controls of critical steps and intermediates	Select	
3.2.P.3.5 Process validation and / or evaluation	Select	<i>Either process validation is described or reference is made to Module 3.2.R, where validation scheme is provided.</i>
3.2.P.4 Control of excipients		
3.2.P.4.1 Specifications	Select	<i>Reference to the Ph.Eur. is sufficient. If an excipient is tested according to Ph.Eur., modules 3.2.P.4.2, 3.2.P.4.3 and 3.2.P.4.4 are N/A.</i>
3.2.P.4.2 Analytical procedures	Select	
3.2.P.4.3 Validation of analytical procedures	Select	
3.2.P.4.4 Justification of specifications	Select	
3.2.P.4.5 Excipients of human or animal origin	Select	<i>Should be consistent with consistent with 2.6.2 of the AF and Mod. 3.2.P.4.5</i>
3.2.P.4.6 Novel excipients	Select	
3.2.P.5 Control of drug product		
3.2.P.5.1 Specification(s)	Select	
3.2.P.5.2 Analytical procedures	Select	<i>In 3.2.P.5.2 and 3.2.P.5.3 - for pharmacopoeial methods, reference to Ph.Eur. is sufficient.</i>
3.2.P.5.3 Validation of Analytical Procedures	Select	

Part 2 – Quality

*Check for either documents in the appropriate indent or a justification for absence has been provided in the quality overview -> If neither is present => **VSI**.*

The purpose of Part 2 validation is to check presence or absence of documents.

3.2.P.5.4 Batch analyses	Select	
3.2.P.5.5 Characterisation of impurities	Select	
3.2.P.5.6 Justification of specification(s)	Select	
3.2.P.6 Reference Standards or Materials	Select	<i>Reference to module 3.2.S.5 is sufficient.</i>
3.2.P.7 Container Closure System	Select	
3.2.P.8 Stability		
3.2.P.8.1 Summary and conclusion	Select	
3.2.P.8.2 Post-approval protocol and stability commitment	Select	
3.2.P.8.3 Stability data	Select	
3.2.A Appendices		
3.2.A.1 Facilities and Equipment	Select	<i>Only applicable to biologicals. No check required for Pharmaceuticals Applications.</i>
3.2.A.2 Adventitious Agents Safety Evaluation	Select	<i>In most cases only applicable to biologicals. If there are materials with TSE risk, information will be included here as well (identical to 3.2.P.4.5 and 3.2.R - TSE tables).</i>
3.2.A.3 Excipients	Select	
3.2.R Regional information (for EU) Process validation scheme for the drug product Medical device information Certificate(s) of suitability (CEPs) Table A (materials of animal origin - TSE) Table B (other material of animal origin) Table C (albumin and other human tissue derived materials)	Select	<i>Process validation: if included in 3.2.P.3.5 only, it's acceptable. TSE tables A, B, C - to be filled in if any materials of human/animal origin were used - consistent with 2.6.2 of the AF and Mod. 3.2.P.4.5. Lactose should be in table B. If no such materials were used, the tables don't have to be included.</i>

ASMF	Select	<p><i>When ASMF procedure is not used, complete active substance information is in Part 2 or Module 3, as applicable.</i></p> <p><i>- If the ASMF is <u>not</u> used, select N/A and <u>leave the ASMF-related boxes below blank</u></i></p> <p><i>- Presence of the ASMF is indicated in the AF 2.5.3. If the ASMF option is ticked but the ASMF is missing (not submitted) = VSI and blocking issue.</i></p> <p><i>- Applicant's part in the ASMF submission must be the same (incl. version and date) as the Applicant's part submitted by the applicant in the dossier for the product.</i></p>
<p><u>To be provided by the ASMF holder:</u></p> <ul style="list-style-type: none"> • ASMF dossier (Applicant's part, Restricted part, Quality Overall Summary (if CTD format) or critical expert report (if Commission Delegated Regulation (EU) 2021/805 format), and Expert's <i>curriculum vitae</i>); • Applicant's Part and Restricted Part are clearly identified in all documents forming part of the ASMF data, by splitting the documents into Open/closed subfolders (AP/RP folders) • Letter of Access (Annex 2 of the Guideline on Active Substance Master File Procedure (EMEA/CVMP/134/02)); • Submission Letter and Administrative Details (Annex 3 of the Guideline on Active Substance Master File Procedure (EMEA/CVMP/134/02)) is provided and contains all sections as in the template; • A commitment to inform the applicant and the EMA of any change in the ASMF to be provided either as a separate letter or within the Letter of Access (Annex 2 of the ASMF Guideline). • The ASMF follows either the VNeS (Commission Delegated Regulation (EU) 2021/805) structure or CTD (human Common Technical Document) structure 	Select Select Select Select Select Select	<p><i>Note: the EMEA/ASMF/xxxxx or EU/ASMF/xxxx reference number should be included in the following documents:</i></p> <ul style="list-style-type: none"> • <i>Letter of Access (Annex 2 of the ASMF Guideline);</i> • <i>Submission Letter and Administrative Details (Annex 3 of the ASMF Guideline) - no section should be deleted, if a section is not applicable, it should be left blank.</i> <p><i>If not included = VSI</i></p> <p><i>Check the version history in section 4 of Submission Letter - does it make sense (i.e. are they submitting the latest version)? Procedure numbers in section 4 should be actual procedures (eg, variations if applicable), not just product numbers.</i></p> <p><i>The technical structure of the ASMF must follow either VNeS or CTD format as per the latest Guideline on eSubmission for Veterinary products</i></p>

<p><u>To be provided by the Applicant:</u></p> <ul style="list-style-type: none"> • Copy of the Letter of Access (Annex 2 of the ASMF Guideline); • Copy of the complete current version of the Applicant’s Part of the ASMF or its revised sections, as applicable, in the relevant part of the dossier; • The Applicant’s Part of the Applicant is identical to the Applicant’s Part of the ASMF holder (check it’s the same version and the same cover page details) • Copy of the commitment from the ASMF holder to inform the applicant and the EMA of any change in the ASMF to be provided either as a separate letter or within the Letter of Access (Annex 2 of the ASMF Guideline). 	<p>Select Select</p> <p>Select</p> <p>Select</p>	<p><i>Letter of Access to be included in annex 5.10 of the application form.</i></p> <p><i>Commitment from ASMF holder to be included in annex 5.11 of the application form if it’s not part of the Letter of Access.</i></p> <p><i>Note: the EMEA/ASMF/xxxxx or EU/ASMF/xxxx reference number should be included in the following documents:</i></p> <ul style="list-style-type: none"> • <i>MAA application form (in the field of the National ASMF reference number or EU ASMF reference Number as appropriate) or variation application form (in the Present and Proposed field);</i> • <i>Letter of Access (Annex 2 of the ASMF Guideline).</i> <p><i>If not included = VSI</i></p>
<p>ASMF – Restricted Part (RP) contents</p>		<p><i>The ASMF contains commercially confidential information not disclosed to the applicant. If some of the sections are missing in the ASMF but are present in the dossier for the MAA (Applicant Part (AP)) (the ASMF holder does not consider it confidential), it is fine - the information must be at least in one place in the dossier (i.e. MAA + ASMF).</i></p> <p><i>In the MAA (Applicant’s part), either limited information or only reference to the Restricted Part (RP) is made for the contents of the sections below. Both options are fine.</i></p> <p><i>If any confidential information is missing, separate VSI to ASMF holder will be sent.</i></p> <p><i>For different versions of the AP (between ASMF and MAA) or any part (as whole) missing - VSI to the applicant as normal.</i></p> <p><i>If CTD, a correlation table indicating the correspondence between CTD sections and Commission Delegated Regulation (EU) 2021/805 structure should be provided by the ASMF holder.</i></p>

		<i>If not = VSI</i>
3.2.S.2.2 Description of Manufacturing Process and Process controls (if CTD) Within part 2C1 if Commission Delegated Regulation (EU) 2021/805	Select	<i>A brief description of the manufacturing process might be included in the applicant's part.</i>
3.2.S.2.3 Control of materials Within part 2C1 if Commission Delegated Regulation (EU) 2021/805	Select	
3.2.S.2.4 Control of critical steps and intermediates Within part 2C1 if Commission Delegated Regulation (EU) 2021/805	Select	
3.2.S.2.5 Process validation and/or Evaluation Within part 2C1 if Commission Delegated Regulation (EU) 2021/805	Select	<i>Only applicable for sterile products</i>
3.2.S.2.6 Manufacturing Process Development Within part 2C1 if Commission Delegated Regulation (EU) 2021/805	Select	
Following documents present either in the RP or in the AP of the dossier		<i>Note: It is mandatory to have them at least in one part of the dossier (restricted or open), otherwise = VSI</i>
3.2.S.3.2 Impurities Within part 2C1 if Commission Delegated Regulation (EU) 2021/805	Select	
3.2.S.4.5 Justification of specifications Within part 2C1 if Commission Delegated Regulation (EU) 2021/805	Select	

CEP – certificate of suitability of the European Pharmacopoeia FOR THE ACTIVE SUBSTANCE (chemical and microbiological quality)	Select	<i>Information on the active substance can be in some cases replaced by a CEP for the active substance. This certificate guarantees quality of the active substance as the Ph.Eur. quality.</i>
Location of the CEP in the dossier	Select	<i>Annex 5.10 and one of the following: Part 2C1: control of starting materials (active substance). If Commission Delegated Regulation (EU) 2021/805 formats used. 3.2.S: if CTD. Reference to Annex 5.10 within the dossier sections above is also acceptable.</i>

		<i>Note: if CEP is used annex 5.11 of the application form should be provided.</i>
Validity of the CEP	Select	<ul style="list-style-type: none"> - Check the EDQM database here for validity of the CEP: https://extranet.edqm.eu/publications/recherches_CEP.shtml - Check version number (consistent with the EDQM database)
Content of the CEP:		
Additional methods/limits	Select	<i>Additional limits/methods (e.g. additional impurities, residual solvents) - description appended to the CEP. These are presented in the form of annexes and should be appended to the CEP. The CEP gives the information on how many lines the CEP has and how many annexes (if any) and how many pages each of these annexes have.</i>
Re-test period	Select	<p><i>Mentioned in CEP - no action</i></p> <p><i>Not mentioned - stability data of the active substance must be submitted:</i></p> <ul style="list-style-type: none"> • <i>Part 2f1 (if Commission Delegated Regulation (EU) 2021/805 structure)</i> • <i>modules 3.2.S.7.1, 3.2.S.7.2 and 3.2.S.7.3 (if CTD)</i>
Declaration of access	Select	<i>It should be completed and signed and/or stamped by the CEP holder.</i>
Parts of Part 2 or Module 3.2.S not covered by a CEP	Select	<ul style="list-style-type: none"> • <i>Manufacturers: to be provided in: 2c1, if Commission Delegated Regulation (EU) 2021/805 structure 3.2.S.2.1, if CTD.</i> • <i>Nomenclature: If CTD: 3.2.S.1.1 - Nomenclature</i> <p><i>Reference to CEP in the above-mentioned cases is not sufficient</i></p> <p><i>Note: CEPs issued on and after 15 July 2013 information on the manufacturers (quality control/in process testing sites, intermediate manufacturers, milling and sterilisation sites) will be appended to the granted CEP. For CEPs granted before 15 July 2013, this information will not be appended to the CEP and</i></p>

		<i>should be included in Part 2 or Module 3.2.S.2.1, as applicable.</i>
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Part 3 – Safety documentation (<i>safety and residues tests</i>)		
<i>Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI.</i>		
Part 3A Safety tests		
Table of contents present, clearly indicating cross-references to part 4 (if applicable)	Select	<i>Synthesis of tests (written summaries) to be included in Part 3.</i>
3.A.1 Precise identification of the product and of its active substance(s)	Select	
3.A.2 Pharmacology		
3.A.2.1 Pharmacodynamics	Select	
3.A.2.2. Pharmacokinetics	Select	
3.A.3 Toxicology		
3.A.4 Other requirements	Select	<i>For antibiotics, lack of this section is a validation issue.</i>
3.A.4.1 Special studies	Select	
3.A.4.2 Observations in humans	Select	
3.A.4.3. Development of resistance and related risk in humans	Select	<i>Data requirements described in this point are related to antibacterial substances and may not be fully applicable to other types of antimicrobial (namely antivirals, antifungals and antiprotozoals)</i>
3.A.5 User safety	Select	
3.A.6 Environmental risk assessment	Select	
3.B.1. Identification of the product	Select	
3.B.2. Depletion of residues (Metabolism and residue kinetics)	Select	
3.B.3. Residue analytical method	Select	

Part 4 –Efficacy documentation (pre-clinical studies and clinical trial(s))

Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI.

Table of contents present, clearly indicating cross-references to part 3 (if applicable)	Select	<i>Synthesis of tests (written summaries) to be included in Part 4.</i>
Part 4.A. Pre-clinical studies		
4.A.1. Pharmacology	Select	
4.A.1.1 Pharmacodynamics	Select	
4.A.1.2 Pharmacokinetics	Select	For generics bioequivalence study (if one is submitted) should be included here and not in Part 3.
4.A.2 Development of resistance and related risk in animals	Select	<i>Only relevant for antimicrobial or antiparasitic products</i>
4.A.3. Dose determination and confirmation	Select	<i>Dose confirmation studies conducted under field conditions might be submitted in part 4B but should be hyperlinked to this section</i>
4.A.4 Tolerance in the target animal species	Select	
Part 4. B Clinical trial(s)		
4.B.2.1 Results of pre-clinical studies	Select	
4.B.2.2 Results of clinical trials	Select	