March 2026
EMA/819958/2022-Rev.3
Veterinary Medicines Division

Validation checklist for initial MAA under Regulation (EU) 2019/6 – biologicals other than immunologicals

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 (not SIAMED) 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. 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
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 Biological substances considered as not requiring an MRL evaluation as per Regulation (EU) 2018/782, with regards to residues of veterinary medicinal products in foodstuffs of animal origin	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010R0037&from=EN List of biological substances not requiring MRL evaluation - Reg 2018-782 (europa.eu)
ATCvet codes	https://www.whocc.no/atcvet/atcvet_index/
EDQM standard terms: (You need EMA's library to give you the username and password. It is used to check the dosage form (=pharmaceutical form) and route of administration.)	https://standardterms.edqm.eu/

Topic	Document
Process for handling new standard term requests received from applicants in the pre-submission phase (or from other sources, also during any procedure):	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).
EUTCT: to check the target species	http://eutct.ema.europa.eu/eutct/showAvailableListsDisplay.do?guestuser=true
Fees guidance published on EMA website (document to be updated yearly)	Fees payable to the European Medicines Agency | European Medicines Agency (europa.eu)
Policy describing administrative issues blocking a positive validation of Marketing Authorisation Applications and I VRAs	EMA/233682/2022 https://docs.eudra.org/webtop/drl/objectId/090142b2852e582d
EMA internal guidance - Brexit – Impact for EMA of the end of the transition period and the EU-UK Trade and Cooperation Agreement	EMA/819958/2022 https://docs.eudra.org/webtop/drl/objectId/090142b284df86a5

3. 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. If no or unsatisfactory responses are received within 2 months from the initial submission date, 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	*If No, request corrected application form and/or PI, as appropriate.*
Confirm Product Shared Mailbox, SIAMED, EURS, DREAM Product Folder are consistent with the Product Name given in the Application Form	Select	*Immediately contact vet applications/ VO and ask for these to be amended. Product Shared Mailboxes are created by eligibility team.*
Are all Annexes as ticked in section '5- Annexed documents' provided?	Select	*Double check with boxes ticked in the individual sections, too. If an Annex is missing issue VSI*
Are the names and address of the Manufacturer(s) of the Finished product and of the Active substance(s) correct through all the dossier, eAF and SIAMED?	Select	
Is the product a novel therapy? If yes, is a Risk Management Plan included?	Select Select	*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 cannot be validated.*

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*** **GENERAL CONSIDERATIONS**		
Has the correct version of the **eApplication Form** been used?	Select	*Use of the correct e-application form is mandatory. Check first page of application form against the latest version.* *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.*

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* **GENERAL CONSIDERATIONS**		
		If missing information is not provided by the validation date, suspend the validation. *The last opportunity for the MAH 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.*
Product (Invented) Name: Has the submitted name been agreed with the CVMP/ Invented Name Check? Is the name the same as indicated in section 2.1.1 and in the Product information.	Select Select	*The invented name should be agreed by CVMP prior submission. However, this is not a validation issue if name not agreed yet. Flag to S/CL* *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/ MAH (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.* *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-*

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* **GENERAL CONSIDERATIONS**		
		information_en.pdf
Cover letter:	Select	
Cover letter: Is the person authorised to communicate on behalf of the applicant during the procedure 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	*If not, or letter not provided/not correct, request corrected application form/letter.*
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	*In case person is different from above ('person authorised to communicate on behalf'*
Declaration on manufacturing sites (attachment to the cover letter) where the applicant confirms that: • The detailed information in relation to the manufacturing sites contained in Part 2/Module 3, is correct in terms of names, addresses and manufacturing activities, and • This information is consistent throughout the dossier, in particular with the corresponding information contained in Part 1 (electronic Application Form, flow-chart in Annex 5.8, QP declaration in Annex 5.19, GMP certificates in Annex 5.9, MIAs or MIAs equivalents in Annex 5.6).	Select	

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* GENERAL CONSIDERATIONS		
Declaration from the applicant that: • All information which is relevant to the evaluation of the veterinary medicinal product concerned is included in the application, whether favourable or unfavourable to the product. In particular, all relevant details related to any incomplete or abandoned study or trial relating to the veterinary medicinal product are given. In addition, all pivotal studies are complete and final reports have been presented and full data of not-completed studies will be provided at a later stage and as soon as available. • All submitted data for this application for marketing authorisation relevant to the quality, safety and efficacy of the veterinary medicinal product, including data publicly available, are not subject to protection of technical documentation.	Select Select	*To be part of the Cover letter.* *If the declaration is missing or MAH cannot declare it due to the fact that the studies are not finalised- clarify it with MAH as a priority. In case studies are not completed- inform SL and Rapporteur/co-Rapporteur immediately. SL/Rapporteur to confirm to a validator whether the validation can be successfully finalised.*
• Applicant established in Ireland to provide a language waiver. The waiver needs to state whether the applicant accept or reject EN as authentic language.	Select	*The waiver needs to be signed by the applicant. For companies established in Ireland, send a question proactively about the waiver (to avoid translations into Irish). In case Irish translation is required flag it up to SL and QRD.* *Guidance and form for waiver:* *https://www.ema.europa.eu/en/veterinary-*

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* **GENERAL CONSIDERATIONS**		
		regulatory/marketing-authorisation/product-information-requirements-veterinary-medicines

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1.1 Eligibility ticked as agreed by CVMP and date correct?	Select	
1.3 Legal basis:	Select	*Check correctness with Letter of Intent(CVMP response to the applicant) and eAF.*
1.3.5 Article 21 - Informed consent application • 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	*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.*

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1.3.7 Article 23 - limited market application	Select	*The letter from CVMP to be included in the dossier Part 1 – Admin Info. The letter should confirm that the product is intended for use in a limited market and that the benefit of availability outweighs the risk associated with the omission of some of the safety or efficacy data*
1.3.8 Article 25 - exceptional circumstances application	Select	*The letter from CVMP to be included in the dossier Part 1 – Admin Info. The letter should provide a justification as to why the benefit of the immediate availability on the market of the veterinary medicinal product concerned outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided.*
1.4 MRL status: For VMPs for food producing animals, has the applicant provided information for the active substance(s) (pharmaceutical products or biological other than immunological product) and excipient (including for immunological products)	Select	*Only to be completed when the target species is/are (a) food-producing animal(s). Only applicable to food-producing animals (check target species in section 2.1.4 of the eAF).* *For biologicals other than immunologicals, information on all constituents should be included.* *Information can be provided either in the field – "Maximum Residue Limits (MRLS) according to Commission Regulation (EU) No. 37/2010" when the MRL has been established by the European Commission or* *- "Biological substance considered as not requiring an MRL evaluation as per Commission Regulation (EU) 2018/782" when the substance has been included in this ad-hoc list or* *- "Application for a Maximum Residue Limit or for an inclusion in the list of biological substances*

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		considered as not requiring an MRL evaluation has been made to the EMA" when the MRL application or inclusion request has been submitted however MRL(s) has not yet been established or the substance has not yet been included in the ad-hoc list. *Additional substances (excipients) may have been declared on the application form. Their MRL status is also checked at validation (for all types of products: non biologicals, biologicals other than immunologicals, immunologicals).*
1.4 MRL status: Is the information concerning established MRLs and/or submitted MRL applications correct?	Select	*For active substance, check in SIAMED – search on the basis of the substance name – whether MRLs have been established (Status: final) or an application has been received (Status: pending or recommended).* *There must be a status for each target species (e.g. bovine, porcine, all mammalian species, all food producing species) and/or relevant food commodity (milk, eggs, honey). 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.* *If however in the "Value" column in SIAMED a "no MRL required" classification applies to this target species (e.g. bovine) it also automatically includes the relevant food commodity (e.g. milk).* *If not, VSI.* *If in doubt, check with S/CL. Flag to S/CL.*
1.5 Additional requests for consideration: Has the applicant	Select	*1.5.1 In case the applicant ticked accelerated*

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provided documents in support of his request for 1.5.1. Accelerated assessment procedure	Select	*assessment, check in SIAMED that this info has been recorded. Accelerated assessment procedure should be added in SIAMED during the eligibility stage so a correct timetable is chosen. 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.*
1.5.2 Prolongation and additional periods of the protection of data: 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))	Select	*If yes, flag it up to Vet Regulatory Affairs*
1.5.3 Prolongation and additional periods of the protection of data: 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	Select	*If yes, flag it up to Vet Regulatory Affairs*

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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 been submitted at least three years before expiration of the protection period laid down in point (d) of Article 39(1))		
1.5.4 Additional data protection: Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a marketing authorisation or for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out)	Select	*If yes, flag it up to Vet Regulatory Affairs*
1.5.5 Additional data protection: Article 40(5) of Regulation (EU) 2019/6 (if a variation involving a change to the pharmaceutical form, administration route or dosage is approved, and additionally assessed to have met a criterion within this Article, the results of the concerned pre-clinical studies or clinical trials shall benefit from four years protection)	Select	*If yes, flag it up to Vet Regulatory Affairs*
2.1.2 Claim for New Active Substance	Select	*If Active Substance ticked as a new active substance:* *- Evidence and justification to be provided in Annex 5.21*

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2.1.3 ATCvet code and Group	Select	*Check correctness on the following link: http://www.whocc.no/atcvet/atcvet_index/* *The pharmacotherapeutic group would usually be the 4th group. It is not the name of the substance.* *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 and standard terms. 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.*

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2.3 **Legal status:** Has the applicant proposed a legal status for its medicinal product? If "not subject to veterinary prescription", is the critical review present?	Select Select	*Applicant to propose something.* *Flag to V- Reg together with the justification by the applicant and copy S/CL in case a proposal contains one of the following:* *- non-prescription* *- restricted* *- special* *An application proposing classification of a veterinary medicinal product as "not subject to veterinary prescription" shall include a critical review of the product characteristics in order to justify the suitability of such classification taking into consideration target and non-target animal safety, public health as well as environmental safety, as outlined in the criteria given in Article 34 (3), points (a) to (g).* *If yes- flag it up to Vet Regulatory Affairs*
2.4.1 **Proposed MAH:** Is the name and address (if mentioned in the proof of establishment (PoE)) of the proposed MAH exactly the same as in the PoE?	Select	*Annex 5.3 has to be provided and the details should be exactly the same as in section 2.4.1. as far as they are given in the PoE. Ignore section for national/decentralised applicant (should be kept unticked/empty)*
Annex 5.3: Proof of establishment: Does the Annex 5.3 duly establish the applicant as being in the EEA?	Select	*Proof of establishment should not be older than 6 months; but can be in any language as long as EN translation is provided).*

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2.4.1 SME status: If yes is ticked, is the Qualification as SME in Annex 5.5 still valid? Information provided in the application are the same in Annex 5.5 and in the formatted table.	Select	
2.4.4 Qualified person for PhV • PSMF reference number and location	Select Select	*There is no requirement to submit the CV of the QPPV as part of Annex 5-20 (or another Annex of the current eAF. This was indeed a requirement in the past and it may be a confusion between previous and current requirements.* *the QPPV CV should be part of the PSMF kept by the applicant/MAH and not part of the submission/PSMF summary. During the assessment the PSMF or parts of it could be requested but this is not a document that should be checked for validation purposes as it is not required.*
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	*Person has to be located in the EEA.*
2.5.2 Proposed Manufacturer of the Finished Product (FP): Is the name and address of the Manufacturer of the FP the same as in Annex 5.8	Select	*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.*
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 Part II (vNees) or Module 3 (eCTD)	Select	*Annex 5.6, 5.9 have to be provided (Checked by inspections). Details of the name and the address mentioned in the Part II or Module 3 to be checked that are the same as in point 2.5.3 of the eAF.*
2.5.3 ASMF and CEP are not applicable to vaccines/ biological products, all the information on the active substance should be provided in the dossier (Part II – vNees or Module 3- eCTD)	Select	*Only CEPs for TSE are applicable to biologicals other than immunologicals (see 2.6.2). In this section both should be ticked with "no"*
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?	Select	*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.* *If VSI – Pharmacopoeia terminology should be used.*

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		This excludes components that are not present in the final dosage form. *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.*
2.6.1 Qualitative and Quantitative composition: **Cross-check with** Part 2, 2a-qual-quant-partic Active substance, excipients Overages	Select	*Notes:* *- 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 quantitative composition needs to be provided (through confidentiality agreement between the applicant and the mixture manufacturer).* *- For liquids, not only concentration per 1 ml needs to be given but also the container size/volume of the product.* *- 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 => flag to S/CL* *- Do not confuse overage and overfill! Overfill = extra volume in parenteral products (injections) to enable withdrawal of the exact dose.* *- Overfill should not be stated in the Application Form – if it is = to be removed.* *No percentage should be listed, exact amount only.*
2.6.2 Materials of animal origin Cross-check with Part 2, 2c4-bio-origin.	Select	*All material of animal origin should be stated including reagents in the active substance manufacture.*
2.6.2 TSE certificate: If applicant has ticked and given the number of a	Select	*Information on excipients to be consistent with Part 2,*

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Ph. Eur. Certificate of suitability, is it/are they duly annexed in 5.12?		*2c4-bio-origin (TSE table A and table B).* *TSE tables applicable only for materials of animal origin* *In EDQM database, it is better to search for the Certificate number (Certificate of suitability for TSE)* *Check the EDQM certificate database online at https://extranet.edqm.eu/publications/recherches_CEP.shtml* *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.*
4.1 Other MAA	Select	*In case of Art 42(4)the point is applicable for CAPs. Check something has been ticked and the corresponding fields have been filled in, and if applicable, Annex 5.15 has been provided.*
4.3 Multiple application: If the company is submitting a duplicate/multiple, has the letter of authorisation from the EC been provided?	Select	*Only possible to validate a multiple application in case at least an amber letter (with conditions to be fulfilled) or a green letter (no conditions) by EC is attached. If a duplicate application is received, please flag to Vet Regulatory Affairs.*

Part 1b – excluding application form		

Dossier- structure		
All documentation should be submitted using file formats that facilitate reviews on screen	Select	*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 has to be searchable.*
Structure of the folders	Select	*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. However, the total number of folder levels of the submission should never exceed three levels.* *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.* *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.*
Files naming	Select	*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.* *Preferably the file name should include the part of the dossier where the document is located. In these*

Dossier- structure		
		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.

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 expert report . 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 to the applicant is necessary. The 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.***		
1c1 Critical expert report - Quality: • Has the report been provided, together with: • CV of the expert • Declaration of his/her professional relationship to the applicant? •	Select Select Select	*Legislation requires educational background, training and occupational experience. That may or may not be a CV.*
1c2 Critical expert report - Safety and Residues: • Has the report been provided, together with: • CV of the expert	Select	*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.*

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 expert report . 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 to the applicant is necessary. The 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.***		
• Declaration of his/her professional relationship to the applicant? • Tabulated summary of all technical documentation and relevant data submitted	Select Select Select	
1c3 Critical expert report - Efficacy: • 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	Select Select Select Select	*Short check if headings of the main subsections are present (pre-clinical, including target animal safety and clinical)*

PART 2 (Quality)

Part 2 – Quality documentation *(physicochemical, biological and 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.***		
Part 2 ToC	Select	*Should be in P2 folder but outside any of the subfolders within P2. (this is also checked by the VNeeS checker)*
2.A Product description		*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.*
2.A.1 Qualitative and quantitative composition	Select	*Including info on:* *- composition (list of all components, their amount on a per-unit basis, the function of the components, and a reference to their quality standards (for example, compendial monographs or manufacturer's specifications)* *- Active substance* *- Excipients (adjuvants, preservatives, stabiliser, colorants etc)* *- Accompanying solvent* *- Containers and closure* *- Devices with which the product will be used or administered*

Part 2 – Quality documentation *(physicochemical, biological and 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.***		
2.A.2 Product development	Select	*Including info on:* *- the choice of composition and the choice of the constituents* *-justification of the inclusion of a preservative* *-the immediate packaging and the suitability of the container and its closure system* *-the microbiological characteristics (microbiological purity and antimicrobial activity) and usage instructions* *- the possible further packaging, outer packaging, if relevant* *-the proposed pack sizes related to the proposed route of administration, the posology and the target species* *- any overage(s) in the formulation to guarantee minimum potency at end of shelf life with justification* *- the selection of the manufacturing process of the active substance and the finished product* *-discussion about differences between the*

Part 2 – Quality documentation *(physicochemical, biological and 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.***		
		manufacturing process(es) used to produce batches used in clinical trials and the process described in the application for marketing authorisation *- when a dosing device is provided with the finished product, the accuracy of the doses(s) shall be demonstrated* *-when an accompanying test is recommended to be used with the finished product (e.g. a diagnostic test), relevant information about the test shall be provided*
2.A.3 Characterisation		
2.A.3.1. Elucidation of structure and other characteristics	Select	*Including info on:* *-Characterisation of a biotechnological or biological substance* *-all relevant information available on the primary, secondary and higher-order structure including post- translational (for example, glycoforms) and other modifications of the active substance* *-details on the biological activity* *-Rational for selection of characterisation methods.*
2.A.3.2. Impurities	Select	*Including information on:* *- qualitative and quantitative description of in-process and product related impurities* *- estimation of clearance*

Part 2 – Quality documentation *(physicochemical, biological and 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.***		
2.B Description of the manufacturing method	Select	*Including information on:* *- The name(s) and address(es) and responsibilities of each manufacturer, including contractors, and each proposed production site or facility involved in manufacture, testing and batch release shall be provided* *-stages of manufacture* *- a process flow chart* *- information on how a batch is defined and on the proposed commercial batch size(s)* *-listing of all the substances at the appropriate steps where they are used* *- the details of the blending and in line process controls* *- documentation on the validation of critical steps or critical assays used in the manufacturing process*
2.C Production and control of starting materials	Select	
2.C.1 Starting materials listed in Pharmacopoeias	Select	
2.C.2 Starting materials not listed in Pharmacopoeia	Select	
2.C.2.1 Starting materials of biological origin	Select	*Including information on:* *-the origin, geographical region, and history of starting materials* *-the origin, general health and immunological*

Part 2 – Quality documentation *(physicochemical, biological and 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.***		
		status of animals used for production *-Freedom from extraneous agents in line with Eur. Ph.* *- GMOs: the quality part of the application shall also be accompanied by the documents required in accordance with* *Directive 2001/18/EC* *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 information here should be consistent with section 2.6.2 of the application form.*
2.C.2.2 Starting materials of non-biological origin	Select	*Including info on:* *- name, description, function, identification, storage*
2.D Control tests during the manufacturing process	Select	*Including info on:* *Test method description, specifications set, validation.*
2.E Control tests on the finished product	Select	*Including info on:* *Test method description, specifications set, validation.*
2.E.1. Finished product specifications	Select	
2.E.2. Method description and validation of release tests	Select	*-general characteristics* *-identification and potency test* *-identification and assay for excipients*

Part 2 – Quality documentation *(physicochemical, biological and 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.***		
		-sterility and purity test *-residual humidity* *-filling volume*
2.E.3. Reference standards or materials	Select	*Information regarding the manufacturing process used to establish the reference material.*
2.F Batch to batch consistency	Select	
2.F.1 Active substance	Select	
2.F.2 Finished product	Select	*Data on three consecutive batches representative of the routine production.*
2.G Stability tests	Select	*Including info on:* *-stability of the antigen* *-stability of the finished product* *-stability of the solvent* *-stability of product in different stages of mixing (Applicable for products administrated in feed)* *-stability of the reconstituted product (applicable for product with solvent)* *-stability of multidose containers (stability data shall be presented to justify a shelf life for the product after it has been broached or opened for the first time)* *-efficacy of preservative*
2.H Other information	Select	*Information relating to the quality of the biological other than immunological veterinary medicinal product not covered by this Section may be included in the dossier.*

Part 3 – Safety documentation (Safety and Residues tests) ***Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI and flag to S/CL.***		
Part 3 Safety documentation (Safety and Residues tests)		
Table of contents present, clearly indicating cross-references to part 4 (if applicable)	Select	
3.A Safety tests	Select	
3.A.1 Precise identification of the product and of its active substance	Select	*- International non-proprietary name (INN)* *- International Union of Pure and Applied Chemistry Name (IUPAC)* *- Chemical Abstract Service (CAS) number* *- Therapeutic, pharmacological and chemical classification* *- Synonyms and abbreviations* *- Structural formula* *- Molecular formula* *- Molecular weight* *- Degree of impurity* *- Qualitative and quantitative composition of impurities* *- Description of physical properties* *- Solubility in water and organic solvents expressed in g/l, with indication of temperature* *- Refraction of light, optical rotation, etc.* *- Formulation of the product*
3.A.2 Pharmacology		*Cross-reference may be*

Part 3 – Safety documentation (Safety and Residues tests) ***Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI and flag to S/CL.***		
		present to studies submitted in Part 4 of the dossier
3.A.2.1 Pharmacodynamics	Select	
3.A.2.2 Pharmacokinetics	Select	
3.A.3 Toxicology	Select	
3.A.3.1 Single dose toxicity	Select	
3.A.3.2 Repeat dose toxicity	Select	
3.A.3.3 Tolerance in target species	Select	
3.A.3.4 Reproductive toxicity including development toxicity	Select	
3.A.3.5 Genotoxicity	Select	
3.A.3.6 Carcinogenicity	Select	
3.A.3.7 Exceptions	Select	*Where a product is intended for topical use, systemic absorption data in the target animal species should be provided. If it is proved that systemic absorption is negligible, the repeated dose toxicity tests, the tests for developmental toxicity and the carcinogenicity tests may be omitted* *unless:* *(a) under the intended conditions of use, oral ingestion of the veterinary medicinal product by the animal is to be expected, or* *(b) under the intended conditions of use, oral exposure of the user of the veterinary medicinal product is to be expected.*

Part 3 – Safety documentation (Safety and Residues tests) ***Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI and flag to S/CL.***		
3.A.4 Other requirements	Select	
3.A.4.1 Special studies	Select	
3.A.4.2 Observation in humans	Select	
3.A.4.3 Development of resistance and related risks in humans, if applicable	Select	
3.A.5 User safety	Select	
3.A.6 Environmental risk assessment 3.A.6.1 Environmental risk assessment of veterinary medicinal products not containing or consisting of genetically modified organisms	Select	
3.A.6.2. Environmental risk assessment for veterinary medicinal products containing or consisting of genetically modified organisms	Select	*Only applicable to GMO products.* *The information is presented in accordance with the provisions of Directive 2001/18/EC, taking into account guidance published by the Commission.* *Documents to be present in the dossier:* *- a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes* *- the complete technical file supplying the*

Part 3 – Safety documentation (Safety and Residues tests) ***Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI and flag to S/CL.***		
		information required under Annexes III and IV to Directive 2001/18/EC; *- the environmental risk assessment* *the results of any investigations performed for the purposes of research or development*
3.B Residue tests	Select	*Only applicable to food-producing species*
3.B.1 Identification of the product	Select	*- Composition* *- The physical and chemical (potency and purity) test results for the relevant batch(es)* *- Batch identification*
3.B.2 Depletion of residues	Select	
3.B.3 Residue analytical method	Select	

Part 4 –Efficacy documentation (pre-clinical and clinical trial(s)) ***Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI and flag to S/CL.***		
Part 4 –Efficacy documentation (pre-clinical and clinical trial(s))		
Table of contents present, clearly indicating cross-references to part 3 (if applicable)	Select	
	Select	
4.A Pre-clinical studies	Select	*The following particulars shall be provided in all pre-clinical study reports.* *(a) a summary;* *(b) a study protocol;*

Part 4 –Efficacy documentation (pre-clinical and clinical trial(s)) *Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI and flag to S/CL.*		
		(c) a detailed description of the objectives, design and conduct to include methods, apparatus and materials used, details such as species, age, weight, sex, number, breed or strain of animals, identification of animals, dose, route and schedule of administration; *(d) a statistical analysis of the results;* *(e) an objective discussion of the results obtained, leading to conclusions on the efficacy and target animal safety of the veterinary medicinal product.* *Omission of any of those data shall be justified.*
4.A.1 Pharmacology	Select	
4.A.1.1 Pharmacodynamics	Select	
4.A.1.2 Pharmacokinetics	Select	*In the target animal species, pharmacokinetic studies are, as a rule, necessary as a complement to the pharmacodynamic studies to support the establishment of safe and effective dosage regimens (route and site of administration, dose, dosing interval, number of administrations, etc.).* *Where pharmacokinetic studies have been submitted under Part 3 of the dossier, cross-reference to such studies may be made.*
4.A.2 Development of resistance and related risk in animals	Select	*For relevant biological veterinary medicinal products (for example, substances with antimicrobial and antiparasitic activity), information on current resistance (if applicable) and on the potential*

Part 4 –Efficacy documentation (pre-clinical and clinical trial(s)) *Check that documents/cross-reference/justification for absence have been provided in the appropriate indent -> If none present => VSI and flag to S/CL.*		
		emergence of resistance should be provided.
4.A.3 Dose determination and confirmation	Select	
4.A.4 Tolerance in target species	Select	
4.B Clinical trials	Select	
4.B.1 General principle	Select	
4.B.2 Documentation	Select	
4.B.2.1 Results of pre-clinical studies	Select	*Info to be provided:* *-a summary* *-a study protocol* *-a detailed description of the objectives, design and conduct to include methods, apparatus and materials used, details such as species, age, weight, sex, number, breed or strain of animals, identification of animals, dose, route and schedule of administration* *- a statistical analysis of the results* *- an objective discussion of the results obtained, leading to conclusions on the efficacy and target animal safety of the veterinary medicinal product*
4.B.2.2 Results of clinical trials	Select	