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COMMISSION IMPLEMENTING REGULATION (EU) 2025/163

of 30 January 2025

amending Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ([1]), and in particular Article 60(1) thereof,

Whereas:

(1) On 8 January 2021 the Commission, as required under Article 60(1) of Regulation (EU) 2019/6 and taking into account the criteria listed in Article 60(2) of that Regulation, adopted Commission Implementing Regulation (EU) 2021/17 ([2]) establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6.

(2) The European Medicines Agency and the Coordination Group on Veterinary Medicinal Products advised the Commission to update the Annex to Implementing Regulation (EU) 2021/17, based upon experience gained and evolving scientifical and technical knowledge.

(3) Commission Delegated Regulation (EU) 2024/1159 ([3]) lays down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals. The product information on veterinary medicinal products authorised before the date of application of that Delegated Regulation are to be adapted if necessary with the requirements of Article 9, paragraphs 1 and 2 of that Delegated Regulation, and therefore a change to the terms of the marketing authorisation may be required. Changes resulting from the necessity to ensure compliance with Delegated Regulation (EU) 2024/1159 that do not require a scientific assessment should be included in the Annex to Implementing Regulation (EU) 2021/17.

(4) The Commission has assessed against the conditions established in Article 60(2) of Regulation (EU) 2019/6 changes that are required in terms of marketing authorisation for the implementation of Article 9 of Delegated Regulation (EU) 2024/1159 to determine which of these changes do not require an assessment and what documentation shall be submitted with the application for the variation not requiring assessment.

(5) Implementing Regulation (EU) 2021/17 should therefore be amended accordingly.

(6) The entry into application of this Regulation should be deferred in order to allow the European Medicines Agency to make the necessary adaptions in the database used for the submission of the variations not requiring assessment.

([1]) OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/2022-01-28.

([2]) Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 7, 11.1.2021, p. 22, ELI: http://data.europa.eu/eli/reg_impl/2021/17/oj).

([3]) Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals (OJ L, 2024/1159, 19.4.2024, ELI: http://data.europa.eu/eli/reg_del/2024/1159/oj).

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2021/17 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 20 April 2025.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 30 January 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2021/17 is amended as follows:

(1) in part A, entry 1 is replaced by the following:

‘**1**	Change in the name or address of:		
a)	— the marketing authorisation holder	The marketing authorisation holder shall remain the same legal entity. The marketing authorisation holder shall already be incorporated in the Union IT systems storing and providing organisational data.	
b)	— a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where specified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	The manufacturing or quality control site and all manufacturing operations shall remain the same. The manufacturer or supplier shall already be incorporated in the Union IT systems storing and providing organisational data (not applicable for starting material and reagent manufacturers/ suppliers).	
c)	— an active substance master file (ASMF) holder	The manufacturing site and all manufacturing operations shall remain the same. The ASMF holder shall already be incorporated in the Union IT systems storing and providing organisational data.	Updated “letter of access” to the Active Substance Master File.’
d)	— a manufacturer of a [novel] excipient (where specified in the dossier)	The manufacturing site and all manufacturing operations shall remain the same.	
e)	— a manufacturer or importer of the finished product (including batch release or quality control testing sites)	The manufacturing or quality control site and all manufacturing operations shall remain the same.	

		The manufacturer or supplier shall already be incorporated in the Union IT systems storing and providing organisational data.	

(2) part B is amended as follows:

(a) entry 1 is replaced by the following:

'**1**	Change in the name or address of a supplier of a packaging component or of a device of the finished product (where mentioned in the dossier):	The supplier shall already be incorporated in the Union IT systems storing and providing organisational data. The manufacturing site shall remain the same.'	

(b) entry 3 is amended as follows:

(i) point (a) is replaced by the following:

'**a)**	— a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for importation, manufacturer responsible for batch release, site where batch control takes place, or supplier of (1) a starting material for an active substance, (2) a reagent or (3) an excipient (when mentioned in the dossier)	The deletion shall not be due to critical deficiencies concerning manufacturing. There shall at least remain one site or manufacturer, as previously authorised, performing the same function as the one(s) concerned by the deletion. There shall at least remain one site or manufacturer responsible for batch release within the European Union or the European Economic Area.'	

(ii) point (i) is replaced by the following:

'**i)**	— a component or components of the flavouring or colouring system	The change shall not have the potential to affect the identity, strength, quality, purity, potency, safety or effectiveness of the finished product.	

		For veterinary medicinal products for oral use, the change does not affect the uptake by target animal species. No change in functional characteristics of the pharmaceutical form, e.g. disintegration time, dissolution profile. Any minor adjustment to the formulation to maintain the total weight shall be made by an excipient which currently makes up a major part of the finished product formulation. Stability studies have been started in line with conditions set out in the relevant guidelines, International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (ICH/VICH), Ph. Eur. etc., (with indication of batch numbers) and relevant stability parameters have been assessed in at least two pilot scale or industrial scale batches and at least 3 months satisfactory stability data are at the disposal of the applicant and the stability profile is similar to the currently registered situation. Assurance is given that these studies will be finalised and that data will be provided immediately to the competent authorities if outside specifications or potentially outside specifications at the end of the approved shelf life (with proposed action). In addition, where relevant, photo-stability testing shall be performed.'	

(c) entry 4 is replaced by the following:

'**4**	Change in the manufacturer of a starting material, reagent or intermediate used in the manufacturing process of the active substance or change in the manufacturer of the active substance where no Ph. Eur. CEP is part of the approved dossier:		Amendment of the relevant section(s) of the dossier

a)	— change in a manufacturer (including relevant quality control testing sites) that is part of the same pharmaceutical group as the currently approved manufacturer	The change shall not be applicable to a sterile active substance or a biological or immunological substance. The new manufacturer shall already be incorporated in the Union IT-systems storing and providing organisational data. For starting materials and reagents the specifications (including in-process controls, methods of analysis of all materials), shall be identical to those already approved. For intermediates and active substance(s) the specifications (including in process controls, methods of analysis of all materials), method of preparation (including batch size) and detailed route of synthesis shall be identical to those already approved. Where materials of human or animal origin are used in the process, the manufacturer does not use any new supplier for which assessment is required of viral safety or of compliance with the current Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.	TSE data as appropriate. Batch analysis data for at least two batches (minimum pilot scale). Qualified person (QP) declaration.
b)	— changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place	The change shall not be applicable to a sterile active substance or a biological or immunological substance. The new manufacturer or site shall already be incorporated in the Union IT-system storing and providing organisational data.	

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		Method transfer from the former to the new site shall have been successfully completed.	
c)	— introduction of a new site of micronisation for the active substance	The change shall not be applicable to a sterile active substance or a biological or immunological substance. The new manufacturer or site shall already be incorporated in the Union IT-systems storing and providing organisational data. The change shall not provoke an adverse change in physico-chemical properties. The particle size specification for the active substance and the corresponding analytical method shall remain the same.	Batch analysis data for at least two comparative batches (minimum pilot scale). Qualified Person (QP) declaration.'
d)	— new storage site of Master Cell Bank or Working Cell Banks	No change shall be made to the storage conditions, the shelf-life and the specifications. The new site shall already be incorporated in the Union IT-systems storing and providing organisational data.	

(d) entry 9 is replaced by the following:

'**9**	Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance:	The change shall not be applicable to a biological or immunological substance. The change shall not adversely affect the reproducibility of the process.	Amendment of the relevant section(s) of the dossier. Test results of at least two batches in accordance with the specifications for the proposed batch size.'

		Changes to the manufacturing methods shall only be those necessitated by scale-up or downscaling, e.g. use of different-sized equipment.	
a)	— up to 10-fold increase compared to the originally approved batch size	The change shall not be applicable to a sterile active substance. The active substance and all intermediates, reagents, catalysts or solvents shall still conform to the approved specifications.	
b)	— downscaling down to 10-fold	The change shall not be the result of unexpected events arising during manufacture or because of stability concerns.	
c)	— more than 10-fold increase compared to the originally approved batch size	The change shall not be applicable to a sterile active substance. The intermediates, reagents, catalysts or solvents used in the process shall remain the same. The active substance and all intermediates, reagents, catalysts or solvents shall still conform to the approved specifications. The change shall not provoke an adverse change in qualitative and quantitative impurity profile, or in physico-chemical properties of the active substance. The change shall not refer to the restricted part of an ASMF.	

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(e) entry 11 is amended as follows:

(i) the introductory wording is replaced by the following:

'**11**	Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance:	The change shall not result from unexpected events arising during manufacture or storage (e.g. new unqualified impurity or change in total impurity). The change shall not be a consequence of any commitment from previous assessments to review specification limits (e.g. made during the procedure for the marketing authorisation application or a variation procedure in accordance with Article 62 of Regulation (EU) 2019/6) unless it has been previously assessed and agreed as part of a follow-up measure in a previous procedure under Regulation (EU) 2019/6."/>	Amendment of the relevant section(s) of the dossier. Comparative table of former and new specification parameters and limits.'

(ii) point (a) is replaced by the following:

'**a)**	— tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance for all veterinary medicinal products including products subject to Official Control Authority Batch Release (OCABR);	The test procedure shall remain the same, or changes in the test procedure shall be minor. The change shall be within the range of currently approved limits.'	

(iii) point (b) is deleted

(iv) points (c) and (d) are replaced by the following:

'**c)**	— tightening of specification limits of the immediate packaging of the active substance	The test procedure shall remain the same, or changes in the test procedure shall be minor.	

		The change shall be within the range of currently approved limits.	
d)	— addition of a new specification parameter to the specification with its corresponding test method for an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	The new test method shall not concern a novel non-standard technique or a standard technique used in a novel way. The new test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance, except if this method is a standard pharmacopoeial microbiological method. The change shall not concern a genotoxic impurity. If it involves the final active substance, other than for residual solvents which shall be in line with ICH/VICH limits, any new impurity control shall be in line with the Ph. Eur. or National Pharmacopoeia of a Member State.	Details of any new analytical method and validation data, where relevant. Batch analysis data on two production batches (3 production batches for biologicals, unless otherwise justified) of the relevant substance for all specification parameters. Where appropriate, comparative dissolution profile data for the finished product on at least one pilot batch containing the active substance complying with the current and proposed specification. For herbal veterinary medicinal products, comparative disintegration data may be acceptable. Justification from the marketing authorisation holder (MAH) or ASMF Holder as appropriate of the new specification parameter and the limits.'

(v) the following point (e) is added:

'**e)**	— addition of a new specification parameter to the specification with its corresponding test method for the immediate packaging of the active substance	The new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Details of any new analytical method and validation data, where relevant. Batch analysis data on two batches of the immediate packaging for all specification parameters. Justification from the marketing authorisation holder or the ASMF Holder, as appropriate, of the new specification parameter and the limits.'

(f) entry 12 is replaced by the following:

'**12**	Minor changes:		
a)	— to an approved test procedure — for active substance or a starting material, reagent or intermediate used in the	The test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent (does not include standard pharmacopoeial microbiological methods).	Amendment of the relevant section(s) of the dossier, including a description of the analytical methodology, a summary of validation data and revised specifications for impurities (if applicable).

	manufacturing process of the active substance; — for the finished product; — for an excipient	Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. There shall be no changes of the total impurity limits; no new unqualified impurities shall be detected. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method).	Comparative validation results, or if justified comparative analysis results showing that the current test and the proposed one are equivalent.
b)	— to an approved test procedure — for the immediate packaging of the active substance or the finished product	Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method). Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Amendment of the relevant section(s) of the dossier, including a description of the analytical methodology and a summary of validation data. Comparative validation results or if justified comparative analysis results showing that the current test and the proposed one are equivalent.
c)	— to an approved test procedure for an in-process test — for active substance; — for the finished product	The test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance.	Amendment of the relevant section(s) of the dossier.

		Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. There shall be no changes of the total impurity limits; no new unqualified impurities shall be detected. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method).	
d)	— in the manufacturing process of an active substance	The change shall not be applicable to a biological or immunological active substance. The change shall not be a change in the geographical source, manufacturing route or production for a herbal veterinary medicinal substance. The change shall not provoke an adverse change in qualitative and quantitative impurity profile or in physico-chemical properties. The synthetic route remains the same, i.e. intermediates remain the same and there are no new reagents, catalysts or solvents used in the process. The specifications of the active substance or intermediates are unchanged. The change shall not refer to the restricted part of an ASMF.	Amendment of the relevant section(s) of the dossier. Batch analysis data (in a comparative tabulated format) of at least two batches (minimum pilot scale) manufactured in accordance with the currently approved and proposed process.

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e)	— in synthesis or recovery of a non-pharmacopoeial excipient (when described in the dossier) or a novel excipient	The excipients and all intermediates, reagents, catalysts, solvents or in-process controls shall still conform to the approved specifications (e.g. qualitative and quantitative impurity profile). Adjuvants and preservatives shall be excluded from the scope of this entry. Synthetic routes and specifications shall be identical, and there shall be no change in physico-chemical properties.	Amendment of the relevant section(s) of the dossier for batch data, comparative data, and specification, as appropriate.
f)	— to an in-process limit range for the finished product	The change shall not be the result of unexpected events arising during manufacture or because of stability concerns. The change shall concern an in-process test, which is also part of the finished product specification at release, and the new in-process limit range shall be within the approved release limit.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new in-process limits.
g)	— to an approved change management protocol of the active substance that does not change the strategy defined in the protocol	The intermediates, reagents, catalysts or solvents used in the process shall remain the same. The active substance and all intermediates, reagents, catalysts or solvents shall still conform to the approved specifications. There shall be no adverse change in qualitative and quantitative impurity profile or in physico-chemical properties. The change shall not refer to the restricted part of an ASMF. The changes shall be within the range of currently approved limits. In case of biological veterinary medicinal products, this change shall be only possible if comparability is not required.	Amendment of the relevant section(s) of the dossier.

		Changes in the geographical source, manufacturing route or production of a herbal substance or herbal preparation of a herbal veterinary medicinal product shall be excluded.	
h)	— to production equipment (when described in the dossier) including processes related to the equipment	The change shall not result in any changes or modifications of the production process or quality of the product.	Amendment of the relevant section(s) of the dossier.
i)	to an approved test procedure — of a measuring or administration device	Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. The method of analysis shall remain the same.	Amendment of the relevant section(s) of the dossier, including a description of the analytical methodology and a summary of validation data. Comparative validation results or if justified comparative analysis results showing that the current test and the proposed one are equivalent.
j)	— in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product	The change relates only to an immediate release solid oral dosage form/oral solution and the veterinary medicinal product concerned is not a biological/immunological or herbal veterinary medicinal product. The manufacturing steps remain the same. The finished product / intermediates / in-process materials used in the manufacture of the finished product shall still conform to the approved specifications. No adverse change in qualitative and quantitative impurity profile or in physico-chemical properties. The new process shall lead to an identica product regarding all aspects of quality, safety and efficacy. Relevant stability studies in accordance with the relevant guidelines shall have been started with at least one pilot scale or industrial scale batch and at least 3 months stability data shall be at the disposal of the applicant.	Amendment of the relevant section(s) of the dossier. For solid dosage forms: dissolution profile data of one representative production batch and comparative data of the last three batches from the previous process; data on the next two full production batches shall be available on request or reported if outside specification (with proposed action). Justification for not submitting a new bioequivalence study in accordance with the relevant guidance on Bioavailability/ Bioequivalence. Batch analysis data (in a comparative tabulated format) on a minimum of one batch manufactured in accordance to both the currently approved and the proposed process.’

(g) entry 13 is replaced by the following:

'**13**	Changes to a test procedure (including replacement or addition):	The active substance/finished product shall not be biological or immunological. Appropriate validation studies have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. The new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Amendment of the relevant section(s) of the dossier and comparative validation data, as appropriate. In the absence of comparative validation data, if justified, comparative analysis results showing that the current test and the proposed one are equivalent. This requirement is not applicable in case of an addition of a new test procedure.'
a)	— for a reagent used in the manufacturing process of the active substance but which does not have a significant effect on the overall quality of the active substance	There shall be no changes to the total impurity limits; no new unqualified impurities shall be detected. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method).	
b)	— for the immediate packaging of the active substance		

(h) entry 14 is replaced by the following:

'**14**	Change in qualitative or quantitative composition of the immediate packaging for the active substance	Sterile, liquid, biological or immunological active substances shall be excluded. The new packaging material shall be at least equivalent to the approved material in respect of its relevant properties. Relevant stability studies have been started under VICH conditions and relevant stability parameters have been assessed in at least two pilot scale or industrial scale batches and at least 3 months	Amendment of the relevant section(s) of the dossier. Appropriate data on the new packaging (e.g. comparative data on permeability, e.g. for O_2, CO_2 moisture), including a confirmation that the material complies with relevant pharmacopoeial requirements or Union legislation on plastic materials and objects in contact with foodstuffs. Where appropriate, proof shall be provided that no interaction between the content and the packaging material occurs (e.g. no migration of components of the proposed material into the content and no loss of components of the product into the pack).

		satisfactory stability data are at the disposal of the applicant at time of implementation. However, if the proposed packaging is more resistant than the existing packaging, the 3 months' stability data do not yet have to be available. These studies shall be finalised and the data shall be provided immediately to the competent authorities if outside specifications or potentially outside specifications at the end of the shelf-life/retest period (with proposed action).	Comparative table of former and new immediate packaging specifications, permeability data and interaction data, as appropriate.'

(i) entry 18 is replaced by the following:

'**18**	Change(s) in the composition (excipients) of the finished product:	The change shall not be applicable to a biological or immunological veterinary medicinal product. The change shall not have the potential to affect the identity, strength, quality, purity, potency, physical characteristics, safety or effectiveness of the finished product. Any minor adjustment to the formulation to maintain the total weight shall be made by an excipient which currently makes up a major part of the finished product formulation. The change shall not affect the functional characteristics of the pharmaceutical form (e.g. disintegration time, dissolution profile).	Amendment of the relevant section(s) of the dossier including stability confirmation.

		Stability studies shall have been started under International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) conditions; relevant stability parameters shall have been assessed in at least two pilot scale or industrial scale batches, and at least three months satisfactory stability data shall be at the disposal of the applicant. The stability profile shall be similar to the currently registered situation. In addition, where relevant, photo-stability testing shall be performed.	
a)	— increase or reduction of a component or components of the flavouring or colouring system	Quantitative change(s) shall not exceed +/- 10 % of the existing concentration of the component. The finished product specification shall only have been updated in respect of appearance, odour or taste and, if relevant, deletion of an identification test. For veterinary medicinal products for oral use, the change shall not negatively affect the uptake by target animal species.	
b)	— any minor adjustment of the quantitative composition of the finished product with respect to excipients	Quantitative change(s) shall not exceed +/- 10 % of the existing concentration of the component. Where relevant, the dissolution profile of the changed product shall be determined on a minimum of two pilot scale batches and shall be comparable to the former one. No significant differences regarding comparability shall occur. For herbal veterinary medicinal products, where dissolution testing may not be feasible, the disintegration time of the	

		changed product shall be comparable to the former one. The change shall not be the result of stability issues and shall not result in potential safety concerns, e.g. differentiation between strengths.	
c)	— addition or replacement of a component or components of the flavouring or colouring system	The finished product specification has only been updated in respect of appearance/odour/taste and if relevant, deletion of an identification test. Any new proposed components shall comply with the relevant applicable Regulations. A new component shall not include the use of materials of human or animal origin. Where applicable, the change does not affect the differentiation between strengths and does not have a negative impact on taste acceptability. For veterinary medicinal products for oral use, the change does not affect the uptake by target animal species. For veterinary medicinal products for food-producing species, the component or components of the flavouring or colouring system shall be allowed in accordance with Regulation (EC) No° 470/2009 and the acts adopted on the basis thereof before implementation of this change. The change shall not be the result of stability issues and shall not result in potential safety concerns (e.g. differentiation between strengths).	Either a Ph. Eur. Certificate of Suitability for any new component of animal origin susceptible to TSE risk or where applicable, documentary evidence that the specific source of the TSE risk material has been previously assessed by the competent authority and shown to comply with the scope of the current Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathies via Human and Veterinary Medicinal Products. The following information shall be included for each such material: name of manufacturer, species and tissues from which the material is a derivative, country of origin of the source animals and its use. Data to demonstrate that the new excipient does not interfere with the finished product specification test methods, if appropriate.’

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(j) in entry 27, point (b) is replaced by the following:

'**b)**	— addition of a new in-process test and limits	Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way. The new test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance, except if this method is a standard pharmacopoeial microbiological method.	Amendment of the relevant section(s) of the dossier for method and validation data, where relevant, batch data and relevant comparative data.'

(k) entry 44 is replaced by the following:

'**44**	Submission of a Ph. Eur. CEP for: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	The finished product release and end of shelf life specifications shall remain the same. Unchanged (excluding tightening) additional (to Ph. Eur.) specifications for impurities (excluding residual solvents, provided they are in compliance with ICH/VICH) and product specific requirements (e.g. particle size profiles, polymorphic form), if applicable. For active substance only, it will be tested immediately prior to use if no retest period is included in the Ph. Eur. Certificate of Suitability or if data to support a retest period is not already provided in the dossier. For a herbal substance or a herbal preparation, the manufacturing route, physical form, extraction solvent and drug extract ratio (DER) shall remain the same.	Amendment of the relevant section(s) of the dossier, including a copy of the updated Ph. Eur. CEP and QP declaration, as appropriate.'

		The manufacturer shall already be approved and incorporated in the Union IT systems storing and providing organisational data (not applicable for starting material, reagent and excipient manufacturers/suppliers).	
a)	Updated certificate	The manufacturing process of the active substance, starting material, reagent, intermediate or excipient shall not include the use of material from human or animal origin, or if it does, any information in relation to material from human or animal origin shall remain unchanged. If the active substance is not a sterile substance but is to be used in a sterile veterinary medicinal product, in accordance with the CEP, the manufacturing process shall not include the use of water during the last steps of the synthesis, or if it does, the quality of water used in the last step of the synthesis shall be unchanged compared to the previous version of the CEP submitted.	
b)	New certificate	The manufacturing process of the active substance, starting material, reagent, intermediate or excipient shall not include the use of material from human or animal origin. The active substance/starting material/reagent/intermediate/excipient is not sterile. If the active substance is not a sterile substance but is to be used in a sterile veterinary medicinal product, in accordance with the CEP the manufacturing process shall not include the use of water during the last steps of the synthesis, or if it does, the active substance shall be free from bacterial endotoxins.	

(l) entry 45 is deleted;

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(m) entry 46 is replaced by the following:

'**46**	Submission of an updated Ph. Eur. TSE CEP of an already approved manufacturer for: — active substance; — starting material, reagent, intermediate used in the manufacturing process of the active substance; — excipient	There has been no change in the source of material. The viral risk assessment is unchanged. If gelatine manufactured from bones is to be used in a veterinary medicinal product for parenteral use, it shall only be manufactured in compliance with the relevant requirements. The manufacturer shall already be approved and incorporated in the Union IT systems storing and providing organisational data (not applicable for starting material, reagent and excipient manufacturers/suppliers).	Amendment of the relevant section(s) of the dossier, including a copy of the updated Ph. Eur. CEP and QP declaration, as appropriate. Where applicable, a document providing information of any materials falling within the scope of the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products including those which are used in the manufacture of the active substance/excipient. The following information shall be included for each such material: Name of manufacturer, species and tissues from which the material is a derivative, country of origin of the source animals and its use. That information shall be included in an updated TSE table A (and B, if relevant).'

(3) part C is amended as follows:

(a) entry 4 is replaced by the following:

'**4**	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products	This change shall only be applicable when no new or additional data is required for an assessment. The proposed changes to Summary of Product Characteristics, Labelling and Package Leaflet shall be identical to wording agreed by the competent authority or the Agency.	Reference to the agreement/assessment of the competent authority or the Agency.'

(b) entry 7 is replaced by the following:

'**7**	Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan	The wording shall be limited to that agreed by the competent authority or the Agency.	Reference to the agreement/assessment of the competent authority or the Agency.'

(c) in entry 10, point (d) is replaced by the following:

'**d)**	— replacement of information on the immediate or outer packaging by an abbreviation or pictogram (including initial addition)	The new abbreviation or pictogram is included in Annex I or Annex II to Implementing Regulation (EU) 2024/875.	

	— replacement of an existing abbreviation or pictogram on the immediate or outer packaging that is not compliant with Commission Implementing Regulation (EU) 2024/875 (*) by another abbreviation or pictogram	The addition does not have a negative impact on the readability of the labelling.	

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(*) Commission Implementing Regulation (EU) 2024/875 of 21 March 2024 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L, 2024/875, 22.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/875/oj).'

(d) in entry 10, the following point (f) is added:

'**f)**	Alignment of the product information with the requirements laid down in article 9 of Commission Delegated Regulation (EU) 2024/1159 (*)	This change shall only be applicable when no new or additional data is required for an assessment.	

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(*) Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals (OJ L, 2024/1159, 19.4.2024, ELI: http://data.europa.eu/eli/reg_del/2024/1159/oj).'

(4) in part D, entry 1 is replaced by the following:

'**1**	Change in the name or address of the VAMF certificate holder for biological products	The VAMF certificate holder shall remain the same legal entity.	Amendment of the relevant section(s) of the dossier, as appropriate.'