Veterinary Harmonisation Group
Veterinary Electronic Submission (VNeeS)
Change Request Process

Version 1.4, July 2016

This document establishes the basis of a change control process that should be in place to effectively evaluate, communicate and execute changes to the European electronic submission specifications used for regulatory submissions for veterinary medicinal products.

The Veterinary Harmonisation Group (VHG) is responsible to decide on changes to the European electronic submission specifications for veterinary medicinal products. Change control should be established to serve the following purposes:

- Evaluate and approve or reject proposed changes to the guidance / specification.
- Ensure implementation of approved changes.
- Represent the interest of all stakeholders who may be affected by the changes.

The Veterinary Harmonisation Group works in co-operation with the Submissions cluster of EU Telematics systems maintenance under the coordination of the Change Management Board (CMB).

Establishment, Mandate and Objectives of Change Control process at the VHG

Two harmonisation groups have been created to harmonise the European electronic submission specifications used for regulatory submissions, i.e. the human and the Veterinary Harmonisation Group. The Veterinary Harmonisation Group (VHG) takes over the tasks from the former Telematics Implementation Group for veterinary eSubmissions, TIGes-vet and its subgroup, the change control group (CCG). It was the latter group who dealt with changes to the specifications. The reason to have a smaller CCG from the TIGes-vet was to speed up the change process. As the new VHG is only slightly larger than the former CCG, there is no need to have the changes to the specifications handled in a subgroup.

The VHG meets virtually each month on a fixed schedule.

At VHG virtual meetings, the group will discuss change requests, and will agree on modifications of the e-submission guidance. Any proposals for changes and the outcome of the discussions will be tracked in a separate tracking table. The VHG will also discuss and make recommendations on other topics or queries in connection to the guideline (e.g. amendments to the Question and Answer document).

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No substantial changes to the relevant guidance or validation criteria will be implemented without prior consultation and agreement of the Veterinary Coordination Group on Mutual Recognition and Decentralised Procedure (CMDv).

The result of the discussion and recommendations by the VHG will be presented by the Chair and co-chair of the VHG and/or other members of the VHG to the Submissions maintenance cluster and CMB.

The detailed description of the change control process and tracking tools for change requests will be publicly available on the EMA veterinary e-submission website on a regular basis.

Implementation strategy for new / changed e-submission requirements

Stability of the European submission requirements is important to ensure efficient electronic submission processes. In order to provide this stability, any releases will follow a specific release strategy that would allow regulatory managers to plan for the future, e.g. by updating their software and business processes in acceptable intervals.

- Major changes to European electronic submission requirements (in particular, implementation of a completely new specification, as in the case of VNeeS) should be publically announced preferably **at least two years** before coming into effect.
- Major updates of any existing specification should be published **at least 6 months** before implementation.
- Minor, non-urgent changes should be collected and combined within one single update of the e-submission guidance which is then amended maximum once per year, if needed.
- Publishing of changes on a shorter timeframe should be restricted to the correction of errors or emergency releases.

Detailed description of procedural steps for VHG meetings, and the change request process:

No.	Action	Responsible	Timeline
1.	Any stakeholder may submit a change request (CR) concerning VHG veterinary guidance documents and Q&A documents via • email to EMA (eSubmission@ema.europa.eu) or • a member of the VHG. The contents of CR submissions must not include confidential information (i.e. on product-related submissions) and should contain at least the following: • Contact information of the person requesting a change, • Date of request, • Clear reference to the section in the document (if applicable, including version and document date) for which the change is proposed, • A detailed description and justification of the request, • If possible, proposals for feasible solutions should be provided. A VNeeS change request template should preferably be used. See link to the template document located on the Veterinary eSubmissions website.	Anybody	Anytime
2.	Check requests received via central email address as regards completeness (clarification from requester may be needed) and send final CR to the VHG Change Coordinator. Check requests received via VHG as regards completeness of content (clarification from requester may be needed) and send final CR to the Change Coordinator.	EMA Member of VHG	Anytime until 14 days before next planned VHG meeting

No.	Action	Responsible	Timeline
3.	Consolidate list of final CRs and classify the change category as "Editorial" or "Content" change in the tracking table. Group CRs and include into Change Request Tracking Table as status "New". If no recommendation already exists for a previous similar request, allocate a CR number in the tracking table. Otherwise send feedback to requester. If new or pending CRs are in the tracking table, the Change Coordinator sends request for an agenda item to EMA including any relevant documents. For simple requests a written procedure by email may be proposed. Final CRs received later than 2 weeks before the VHG meeting date may not be discussed at that VHG meeting, but at the next meeting.	Nominated member of the VHG (Change Coordinator) (Contact to requestor by initial VHG contact)	Anytime until 7 days before next planned VHG meeting
4.	EMA sends draft agenda including any pre-meeting documents to VHG members and confirms VHG meeting date. In case of written procedures EMA requests feedback from VHG members and provides consolidated responses to VHG Chair (go to Step 9).	EMA	Anytime until 7 days before planned VHG meeting date
5.	VHG evaluates the urgency/priority of requests and their business impact and makes recommendation (recommendation is added to tracking table).	VHG	During the VHG meeting
6.	CR is postponed to next VHG meeting in case, e.g. a. more complex requests may need further consultation with relevant experts from stakeholders or regulators b. or VHG member may need to contact the requester for further clarifications c. or if VHG decides that other groups like CMDv or Notice to Applicants Group need to be involved These CRs and CRs that need further discussion in the VHG are marked as "Pending".	VHG	During the VHG meeting
7.	In case of pending CRs collect feedback and go to step 4.	(Contact to requestor by initial VHG contact)	Anytime until 14 days before next planned VHG meeting

No.	Action	Responsible	Timeline
8.	If no agreement is reached within VHG, request is returned to the next VHG agenda for further discussion (go to step 4).	VHG Chair	At the VHG meeting
9.	Upon final VHG decision, date of VHG recommendation is added to the tracking table. Add or revise recommendation as necessary. Status of request in tracking table is set accordingly a. in case of agreement with request as "Accepted", b. in case of disagreement as "Rejected".	Change Coordinator	Within 7 days after the VHG meeting
10.	Feedback on recommendation is given to requester.	Initial VHG contact	Within 7 days after the VHG meeting
11.	Draft "working guidance documents" are kept updated by VHG as regards all agreed text changes.	Change Coordinator / EMA	Within 14 days after the VHG meeting
12.	In case of pending changes normally maximum once a year a revised version of a guidance document is published on the EMA website (unless urgent corrections). See section on “Implementation strategy for new / changed e-submission requirements” for further details. (The date for coming into effect or the need for a public consultation has to be agreed by VHG.) Inform VHG Chair and co-chair upon publication.	EMA	Anytime (maximum once yearly in case of minor changes)
13.	Changes of the Q&A are implemented with their publication on the EMA e-submission website. Inform VHG Chair and co-chair upon publication.	EMA	Anytime with next update
14.	Publish on the EMA e-submission website current version of the tracking table.	EMA	Within 4 weeks after the VHG meeting (not more than 4 times a year)