Veterinary Electronic Submission (VNeeS)
Change Control Group and Change Request Process

Version 1.3, December 2011

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 TIGes veterinary subgroup is accountable 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.

As such the TIGes veterinary subgroup functions as a Change Control Board.

Establishment, Mandate and Objectives of Change Control Group (CCG)

During the June 2010 meeting of the TIGes veterinary subgroup, it was decided to delegate pre-discussion of matters of change control and change requests to a new subgroup of the TIGes vet subgroup, i.e. the Change Control Group (CCG). As such, the CCG is following the mandate and objectives of the TIGes vet subgroup related to changes to the European electronic submission specifications.

The objective was to speed up the change process and ensure that the TIGes vet subgroup would not spend too much time on details during plenary sessions, and to ensure that all details are correctly tracked. The CCG sub-group works and meets usually via virtual media (Vitero). Frequency of meetings is based on the amount of upcoming change requests, and would usually not exceed 4 meetings per year, aligned to the meeting frequency of the TIGes vet subgroup.

At CCG meetings, the CCG will discuss change requests, and will agree on recommendations to the TIGes vet subgroup for 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 CCG 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).

The result of the discussion and recommendations by the CCG will be presented by the Chair of the CCG and/or other members of the CCG to the TIGes vet subgroup plenary meeting. All final decisions

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telep□one +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

remain within the TIGes vet subgroup at which level wider consultation with other stakeholders can take place, where necessary.

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

Composition of CCG

Core members of the CCG should be assigned from the TIGes vet subgroup, consisting of representatives of regulatory authorities (NCAs, EMA) and stakeholders. All stakeholders present in the TIGes vet subgroup (AVC, EGGVP and IFAH-Europe) should be able to nominate a member to the CCG. For each meeting, a balanced representation of representatives from national agencies and industry should be aimed for. Other members of the TIGes vet subgroup or experts who are not members of the TIGes vet subgroup may be consulted and invited to the meetings. However, the number of participants at CCG meetings should be limited to allow efficient discussion. Nominations of deputy representatives or additional experts to be invited for a specific meeting are agreed with the Chair of the TIGes vet subgroup and the chair of the CCG. A list of all invited participants will be included in the CCG agenda and communicated to the TIGes vet subgroup.

The chair of the CCG will be elected within the CCG, and confirmed by the TIGes vet subgroup for a term of three years. The composition of the group will also be reviewed every 3 years.

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 CCG meetings, and the change request process:

No.	Action	Responsible	Timeline
1.	Prepare draft schedule of next year's CCG meeting dates (CCG meetings usually take place at least 4 weeks before a TIGes vet sub group meeting) and agree with CCG members.	EMA and CCG chair	Anytime, approx. 1 year ahead of CCG meetings
2.	Any stakeholder may submit a change request (CR) concerning TIGes veterinary guidance documents and Q&A documents via o email to EMA (esubmission@ema.europa.eu) or o a member of the TIGes veterinary subgroup . The contents of CR submissions must not include confidential information (i.e. on product-related submissions) and should contain at least the following: o Contact information of the person requesting a change, o Date of request, o Clear reference to the section in the document (if applicable, including version and document date) for which the change is proposed, o A detailed description and justification of the request, o If possible, proposals for feasible solutions should be provided.	Anybody	Anytime
3.	Check requests received via central email address as regards to completeness (clarification from requester may be needed) and send final CR to chair of CCG. Check requests received via TIGes vet subgroup or CCG member as regards completeness of content (clarification from requester may be needed) and send final CR to chair of CCG.	EMA initial TIGes vet sub group/ CCG contact	Anytime until 14 days before next planned CCG meeting

No.	Action	Responsible	Timeline
4.	Consolidate list of final CRs. Group CRs and include into Change Request Tracking Table as status "New", and inform CCG members. If new or pending CRs are in the tracking table, CCG chair sends request for a CCG meeting to EMA including draft agenda and any pre-meeting documents. For simple requests a written procedure by email may be proposed. Final CRs received later than 2 weeks before the CCG meeting date may not be discussed at that CCG meeting, but at the next meeting.	CCG chair	Anytime until 7 days before next planned CCG meeting
5.	EMA contacts CCG members to organize Telco / Vitero meeting, sends draft agenda including any pre-meeting documents and confirms CCG meeting date. In case of written procedures EMA requests feedback from CCG members and provides consolidated responses to CCG chair (go to Step 10).	EMA	Anytime until 7 days before planned CCG meeting date
6.	CCG finally classifies the request: a. If no recommendation already exists for a previous similar request, allocate a CR number in the tracking table. Otherwise send feedback to requester. b. CCG classifies the change category as "Editorial" or "Content" change in the tracking table.	CCG (Contact to requestor by initial CCG / TIGes vet sub group contact)	During the CCG meeting
7.	CCG evaluates the urgency/priority of requests and their business impact and makes draft recommendation (recommendation is added to tracking table). Status of request in tracking table is set accordingly (including CCG meeting date): a. in case of agreement with request as "Accepted", b. in case of disagreement as "Rejected".	CCG	During the CCG meeting
8.	CR is postponed to next CCG meeting in case a. more complex requests may need further consultation with relevant experts from stakeholders or regulators or b. CCG member may need to contact the requester for further clarifications. These CRs and CRs that need further discussion in the TIGes vet sub group are marked as "Pending".	CCG	During the CCG meeting

No.	Action	Responsible	Timeline
9.	In case of pending CRs collect feedback and go to step 4.	(Contact to requestor by initial CCG / TIGes vet sub group contact)	Anytime until 14 days before next planned CCG meeting
10.	Inform chair of TIGes vet sub group about CCG recommendations for Final and Rejected CRs or CRs that need discussion on TIGes vet sub group level for addition to agenda of next TIGes vet sub group meeting.	CCG chair	anytime until 14 days before the TIGes-vet sub group meeting
11.	Evaluate, discuss, revise (if applicable) and finally decide on the analysis made by the CCG. Decide whether other groups like CMDv or Notice to Applicants Group need to be involved.	TIGes-vet sub group	At the TIGes-vet sub group meeting
12.	If no agreement within TIGes vet sub group, request is returned to the next CCG agenda for further discussion (go to step 4).	CCG chair	At the TIGes-vet sub group meeting
13.	If CR is agreed, date of agreement with TIGes vet sub group is added to the tracking table. Revise final recommendation where necessary.	CCG chair	Within 7 days after the TIGes-vet sub group meeting
14.	Feedback on recommendation is given to requester.	Initial CCG / TIGes vet sub group contact	Within 7 days after the TIGes-vet sub group meeting
15.	Draft "working guidance documents" are kept updated by CCG as regards all agreed changes.	CCG chair	Within 14 days after the TIGes-vet sub group meeting
16.	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 TIGes vet sub group.) Inform CCG and TIGes vet sub group chairs upon publication.	EMA	Anytime (maximum once yearly in case of minor changes)
17.	Changes of the Q&A are implemented with their publication on the EMA e-submission website. Inform	EMA	Anytime with next update

No.	Action	Responsible	Timeline
	CCG and TIGes vet sub group chairs upon publication.		
18.	Upon publication of the final revised guidance/revised Q/A mark CR as status "Implemented" in the tracking table stating the agreed date of implementation.	CCG chair	Anytime before following CCG meeting.
19.	Publish on the EMA e-submission website current version of the tracking table.	EMA	Within 4 weeks after the TIGes-vet sub group meeting