

# Veterinary Electronic Submission (VNeS) Change Request Process

Version 1.0, November 2010

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.	<p>Any stakeholder may submit a <u>change request (CR)</u> concerning TIGes veterinary guidance documents and Q&amp;A documents via</p> <ul style="list-style-type: none"> <li>o email to EMA (esubmission@ema.europa.eu) or</li> <li>o a member of the TIGes veterinary subgroup or the Change Control Group (CCG).</li> </ul> <p>The contents of CR submissions must not include confidential information (i.e. on product-related submissions) and should contain at least the following:</p> <ul style="list-style-type: none"> <li>o Contact information of the person requesting a change</li> <li>o Date of request</li> <li>o Clear reference to the section in the document (if applicable, including version and document date) for which the change is proposed</li> <li>o A detailed explanation and justification of the request</li> <li>o If possible, proposals for feasible solutions should be provided.</li> </ul>	Anybody	Anytime
3.	<p>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.</p> <p>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.</p>	<p>EMA</p> <p>initial TIGes vet sub group/ CCG contact</p>	Anytime until 14 days before next planned CCG meeting
4.	<p>Consolidate list of final CRs.</p> <p>Include CRs into Change Request Tracking Table as</p>	CCG chair	Anytime until 7 days before next planned



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	<p>status "New", and inform CCG members.</p> <p>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.</p> <p>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.</p>		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.	<p>CCG finally classifies the request:</p> <p>a. If no recommendation already exists for a previous similar request, allocate a CR number in the tracking table. Otherwise send feedback to requester.</p> <p>b. CCG classifies the change category as "Editorial" or "Content" change in the tracking table.</p>	<p>CCG</p> <p>(Contact to requestor by initial CCG / TIGes vet sub group contact)</p>	During the CCG meeting
7.	<p>CCG makes draft recommendation for requests (recommendation is added to tracking table).</p> <p>Status of request in tracking table is set accordingly (including CCG meeting date):</p> <p>a. in case of agreement with request as "Accepted",</p> <p>b. in case of disagreement as "Rejected".</p>	CCG	During the CCG meeting
8.	<p>CR is postponed to next CCG meeting in case</p> <p>a. more complex requests may need further consultation with relevant experts from industry or regulators or</p> <p>b. CCG member may need to contact the requester for further clarifications.</p> <p>These CRs and CRs that need further discussion in the TIGes vet sub group are marked as "Pending".</p>	CCG	During the CCG meeting
9.	In case of pending CRs collect feedback and go to step 4.	(Contact to requestor by initial CCG / TIGes vet sub	Anytime until 14 days before next planned

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		group contact)	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 once a year a revised version of a guidance document is published on the EMA website (unless urgent corrections). 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 or latest once yearly
17.	Changes of the Q&A are implemented with their publication on the EMA esubmission website. Inform CCG and TIGes vet sub group chairs upon publication.	EMA	Anytime with next update
18.	Upon implementation of CR (publication of revised guidance/revised Q/A) mark CR as status "Implemented" in the tracking table stating the date of publication.	CCG chair	Anytime before following CCG meeting.
19.	Publish on the EMA esubmission website current version of the tracking table.	EMA	Within 4 weeks after the TIGes-vet sub

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			group meeting