Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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BEST PRACTICE GUIDE

for

Veterinary Decentralised Procedure (DCP)

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INTRODUCTION

With the entry into force of Directive 2004/28/EC amending Directive 2001/82/EC, a new procedure, the Decentralised Procedure (DCP) was created. Except for cases where the Centralised Procedure is either compulsory or optional, if an Applicant/Marketing Authorisation Holder wishes to have a Marketing Authorisation (MA) recognised in more than one Member State (MS), then either the Mutual Recognition Procedure (MRP) if the product already has a MA in the Community, or the Decentralised Procedure, if the product is not authorised in the Community should be used.

All timelines in this BPG are based on calendar days.

1. AIM AND SCOPE

This Best Practice Guide (BPG) has been prepared for use in a DCP by the Reference Member State (RMS), Concerned Member States (CMS) as well as the applicant, in order to facilitate the smooth running of the procedure.

2. REFERENCES AND RELATED DOCUMENTS

- Directive 2001/82/EC[1];
- Notice to Applicants, Volume 6A, Chapter 2[2];
- Guideline on the definition of a potential serious risk to human or animal health or for the environment[3];

[A full list of CMDv documents related to this BPG can be found at the end of the document].

3. DESCRIPTION OF THE PROCEDURE

The DCP is divided into four steps: pre-procedural step, assessment step I including the clock-stop period, assessment step II and a national step. An additional step (referral to CMDv) will occur when agreement on a positive Assessment Report of the RMS cannot be reached by all CMSs on Day 210.

The RMS may close the procedure at any time point during the procedure, if consensus is reached between MS.

3.1. Pre-procedural Step and General Requirements

All communications between the RMS and CMS will be sent by e-mail in accordance with the relevant guidance documents (see Annex 1).

All competent authorities should maintain CTS (Communication Tracking System) and ensure that the information is updated continuously throughout the procedure.

With respect to communications from the applicant, submission of the applicant's responses or other clarification by e-mail, this does not automatically mean that paper copies or electronic submission in an agreed format are not needed. It is the duty of the applicant to check how MSs need to receive the documentation (see the CMDv website).

[1] as amended by Directive 2004/28/EC
[2] Notice to Applicants (Volume 6A) is available on the website of the European Commission: http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-6/index_en.htm
[3] Guideline is available on the website of the European Commission: http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-6/index_en.htm

Discussion with the future RMS

It is strongly recommended that the applicant should discuss the proposed DCP with the chosen RMS, at least three months before the intended start date.

The RMS should give regulatory and scientific advice or recommendations to the applicant in order to facilitate the procedure.

At this stage, the RMS should make the applicant aware that in some Member States multi-lingual labels are necessary. Furthermore, in some cases the Applicant may seek to have combined labels in more than one Member State. In such cases, a space restriction might exist and a solution has to be sought in trying to fulfil the legal requirements for harmonisation, the national legal requirements and the safe use of veterinary medicinal products. The submission of mock-ups reflecting the maximum number of intended languages to be included on multilingual packs (or a minimum 3 x EN) can facilitate this process.

If a combined label for more than one MS is intended, the applicant should also be advised to seek agreement on the name of the product with the CMS(s) affected, as early as possible.

No more than 3 months before the intended start date, the RMS creates the procedure in CTS by allocating a procedure number to the DCP application (in accordance with the numbering system described in Chapter 2, Volume 6A of the NtA and CMDv/SOP/003 – Allocation of the MRP/DCP application number). The RMS will inform the applicant accordingly.

The applicant should notify the future CMS of the intention to submit an application.
The RMS will inform the CMS one month before the start of the procedure of the proposed start date and timetable.

If it is foreseen that there may be different views among CMS regarding the legal basis of the application, the matter can be discussed at a meeting of the CMDv prior to the submission of the application.

Submission to CMS

The applicant will submit the application simultaneously to the competent authority of each of the Member States where a marketing authorisation is to be sought.

The applicant is required to give an assurance, usually in the cover letter accompanying the application that the dossier as submitted is identical in all MS concerned. A template for this cover letter is available in the CMDv website.

The application should be made in accordance with the legal basis applied for. Guidance on format, appropriate number of copies of the dossier, language requirements, fees etc. can be found in the CMDv website.

In case of electronic submissions the “Guideline on the specifications for provision of an electronic submission (e-submission) for a veterinary medicinal product also applies.

Text proposals for SPC, PL and labelling in English are acceptable at this stage. The submission of mock-ups reflecting the maximum number of intended languages on multilingual packs is strongly advisable (in any case minimum 3 x EN).

The applicant should notify the RMS of the dates of dispatch and receipt of the dossier. It is the duty of all CMS to react immediately if they have not received the application.

In the case of a generic application, where the reference product is not authorised in a particular MS, that MS may request minimum information on the reference product, as defined in CMDv/GUI/006. The MS where the reference product is authorised shall transmit within a period of one month after receipt of the request, confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation (so-called "minimum information").

Validation

Once the RMS is informed that the application has been submitted to all CMS and dispatch has been completed, the RMS will start the validation period by sending an e-mail to all CMS and to the applicant indicating the proposed time table for Assessment step I.

The CMDv has agreed to follow the automatic validation procedure for DCP applications as outlined in CMDv/BPG/008. The CMS has the duty to update the status of the CTS record continuously to reflect the current (validation) status.

All MS involved in the procedure should validate the application within 14 calendar days. By day 7 of the validation period the RMS will update the applicant and the CMS with the validation status and inform about the planned start date. The CMS who have not validated, will have 7 days to confirm validation. If no confirmation is received, the RMS will assume the application is valid.
Validation issues of an administrative and/or regulatory nature should be notified to the RMS, CMS and applicant by e-mail as soon as possible and within 14 days following the receipt of the application (see also CMDv/BPG/008).

If a CMS has advised that the application is not valid, the clock will not be started until that CMS confirms that the issue(s) has/have been resolved and the application is valid. The CMS must inform the RMS and applicant that the application has become valid immediately after the missing information or fee has been supplied.

If the application is still not considered valid after supplements, the applicant will be advised to withdraw the application in the relevant MS within 14 days.

If the application is considered invalid in the RMS, but other MS concerned have validated, the applicant may choose another RMS or withdraw the application from all MS concerned.

In any case, the procedure cannot be started until all validation issues have been resolved, unless the objecting MS has accepted a suitable commitment to resolve them.
At the end of the validation phase the RMS will inform the applicant and the CMS of the start date and confirm the timetable for the procedure.
At this point the RMS will check and update the information and fill in procedure start date (Day 0) in the CTS.

3.2. Assessment step I (120 days)

The Assessment Step I corresponds to the 120-day period for preparing the Draft Assessment Report (DAR) and drafts of the SPC, PL and labelling as stated in Article 32.3 of Directive 2001/82/EC.

RMS assessment by Day 70

The RMS will start the assessment once the procedure has been started.

The Assessment Report (AR) should be written according to the relevant CVMP guideline concerning preparation of assessment reports for veterinary medicinal products. The English versions of the draft SPC, PL and labelling should follow the QRD template for product information.

The RMS will forward a Preliminary Assessment Report (PAR) together with the drafts of SPC, PL and labelling to the CMS and the applicant within 70 calendar days after the start of the procedure. The PAR will include a draft List of Questions (LOQI) as proposed by the RMS.

CMS comments by Day 100

The involvement of all CMS is recommended to allow the applicant to deal with the majority of issues whilst the clock is stopped. This is especially important if the CMS believes there may be issues of potential serious risk (PSR) to human or animal health or for the environment.

By Day 100, i.e. not later than 30 calendar days after receipt of the PAR and drafts of the SPC, PL and the labelling, each CMS should identify and communicate to the RMS and other CMS their comments on the PAR, the proposed SPC, PL and labelling and, if necessary, on the dossier. CMS may propose additional questions to be added to the draft LOQI. All questions should be carefully screened within the competent authority. CMSs should avoid repetition of the same/similar questions already proposed by the RMS or other CMSs.

At every stage of the procedure, all CMS comments containing confidential information should be notified (in the title of the e-mail) so that the RMS will be aware of what comments can be sent to the applicant. In such cases, it might be advisable to send two emails, one containing the confidential comments and the other the non-confidential comments.

Compilation of the list of questions by Day 105

Between Days 100 and 105 of the procedure the RMS will compile a List of Questions (LOQI) for the applicant according to the agreed format (CMDv/TEM/001).

During this time the RMS may initiate discussions with any CMS regarding points and comments that need clarification. The reports of these discussions should be circulated to all MS concerned.

Normally all questions from CMS are included in the LOQI except where questions repeat those already proposed by the RMS or another CMS. Similar questions from different CMS can be combined by the RMS. If the RMS decides to leave out questions from CMS, this should be justified and the CMS informed.

When compiling the LOQI, the RMS will not identify the name of the CMS posing the question. It is recommended that the comments will be presented in one consolidated list of questions whenever possible. The LOQI should indicate if confidential questions to the RMS and/or the ASMF holder have been posed so that the applicant is aware.

On Day 105 the RMS will send the LOQI to the applicant and CMS and stop the clock accordingly. If applicable, the RMS will send a confidential LOQ on the Active Substance Master File (ASMF) to the CMS and ASMF holder. In such cases the RMS should also inform the applicant, indicating whether the confidential questions relate to PSR issues and/or points for clarification.

Clock-off period

The clock-off period will be up to three months for the applicant to prepare their responses to the LOQI and amend the SPC, PL and labelling as appropriate. The clock-off period can be extended by an additional three months, if justified and agreed with the RMS. Only in exceptional circumstances may the clock-off period exceed six months. Extensions to the clock-off period beyond six months must be fully justified by the applicant and agreed by the RMS and all CMS.

The applicant's submission of the Day 106 response should be carefully arranged with the RMS. Some Member States acting as RMS allow submission of draft responses for pre-assessment. Other Member States require submission of the final response in advance of the official submission to all CMSs. In all cases, the applicant should agree the date of submission of the final response with the RMS.

The applicant will complete the response to the LOQI by writing the response after each question in the document received from the RMS. This document (Applicant's response to the LOQI) will be sent by e-mail to the RMS, who will immediately forward it by e-mail to the CMS. The applicant will simultaneously send the response in hard copy and/or electronic submission where accepted including any attachments, to the RMS and all CMS.

All changes to the SPC, PL and labelling proposed by the applicant must be done using the 'track changes' tool in the originally proposed versions in order to record changes made throughout the procedure.

The applicant is allowed to submit new data in response to the questions raised by the MS concerned during the procedure.

After receiving the full and complete response from the applicant the RMS is entitled to a 14 day period for validation of the applicant's response. Subsequently the RMS will inform the applicant and CMS by e-mail that the clock has re-started. An updated timetable will be included. The time table will comply with the published start dates for DCP phase II and thus influence the start of RMS assessment.

The RMS updates the CTS record with the date of Day 106.

From Day 106, the RMS has 14 calendar days to update the PAR. By Day 120, the resulting DAR and evaluation of the draft SPC, draft PL and labelling must be prepared by the RMS.

3.3. Assessment step II (90 days)

RMS Draft Assessment Report, draft LOQII and drafts of SPC, PL and labelling on Day 120 (Day 0)

On Day 120 of the procedure, the RMS will circulate to the applicant and the CMS the DAR, including the RMS assessment of the applicant's response to the LOQI, draft Step II List of Questions (LOQII), draft SPC, PL and labelling together with its recommendation on the product.

In the beginning of this document the RMS will clearly indicate whether the application is approvable or not after assessing the applicant's response. The RMS will also indicate the areas where major issues/questions are not resolved (see CMDv/TEM/001).
Day 120 corresponds to Day 0 of the Assessment Step II (the Mutual Recognition phase) and is set to match the agreed start dates for MRP and DCP.

CMS comments by Day 145 (Day 25)

As soon as possible, but no later than Day 145, each CMS should identify and communicate to the RMS, the other CMS and the applicant (via RMS) any outstanding concerns regarding a potential serious risk to human or animal health or for the environment, which, if unresolved, would lead to a referral to CMDv. Comments would include major issues regarding the DAR, the quality, safety or efficacy of the product, or the draft SPC, PL and/or labelling.

All questions should be presented in the format agreed for the Response Report (CMDv/TEM/007) and should include a clear explanation of the grounds for the concern(s) raised and how this constitutes a potential serious risk. Other points for clarification together with considerations on the draft SPC, PL and labelling will also be included in this response report.

All questions should be carefully screened within the competent authority in order to minimise the number of questions.

The RMS shall forward these Day 145 comments from each CMS directly to the applicant as soon as they are received, before the preparation of the LOQII.

List of questions by Day 150 (Day 30)

The RMS shall prepare the LOQII according to the agreed CMDv template (CMDv/TEM/001) clearly identifying and separating concerns regarding PSR, points for clarification and considerations on SPC, PL and labelling. Questions will not be combined but will be included verbatim identifying each CMS. The LOQII should indicate if confidential questions to the RMS and/or the ASMF holder have been posed so that the applicant is aware. This LOQII is sent to the applicant and CMS by Day 150 of the procedure.
If applicable, the RMS will send a confidential LOQII on the ASMF to the CMS and ASMF holder. In such cases the RMS should also inform the applicant, indicating whether the confidential questions relate to PSR issues and/or points for clarification.

Applicant response by Day 170 (Day 50)

In accordance with the agreed format the applicant will send the response document (Resp-LOQII) by Day 170 at the latest by e-mail to the RMS, who will forward this response to all the CMS. Applicants must ensure that necessary paper/electronic copies as published on the CMDv website arrive by Day 170 at the latest in all CMS.

All changes to the SPC, PL and labelling proposed by the applicant must be done using the 'track changes' tool in the originally proposed versions in order to record changes made throughout the procedure. The applicant should note that changes to the proposed product name initiated by the applicant or by a Concerned Member State during the procedure should be clearly and immediately communicated by the applicant to the CMS affected by the proposed change in a separate mailing, copying the Reference Member State. An updated exchange page of the application form and annex 5.18 will have to be submitted to the NCA if a new name is agreed during the procedure.

RMS assessment of the Applicant response by Day 190 (Day 70)

The RMS should evaluate responses given by the applicant to the issues raised by the MS concerned and communicate this evaluation (AR-Resp-LOQII) in writing to all CMS and to the applicant by Day 190 at the latest (by e-mail).

In the beginning of this document the RMS will clearly indicate whether the application is approvable or not after assessing the applicant's response. The RMS will also indicate the areas where major issues/questions are not resolved (see CMDv/TEM/001).

MS comments before the CMDv meeting by Day 195 (Day 75)

All MS should send their remaining issues by Day 195 at the latest to the RMS, the other CMS and the applicant (via the RMS) in order for the RMS to prepare for a consultation with CMS as to whether a virtual product discussion is necessary.

At the CMDv meeting on Day 197 (Day 77)

The RMS will consult CMS in order to agree whether a virtual product discussion is necessary during the following week; usually on the Monday/Tuesday i.e. on Day 201/202 (81/82). At the request of the RMS/CMS the product discussion may, where deemed necessary/appropriate, be held during the CMDv plenary meeting. In these special cases the RMS is required to liaise with the Secretariat as soon as possible.

Procedure related outstanding major questions that are considered to be of a principal nature may also be highlighted and presented by RMS/objecting CMS at the CMDv plenary meeting.

If there are no issues of potential serious risk to resolve, it is not necessary for the application to be discussed unless the decision to hold a discussion has been agreed by the Member States concerned. The RMS will announce cancellations at the CMDv plenary meeting and by e-mail communicate the same information via the List V-CMD, List V-MRNA and CMDv@ema.europa.eu. In principle, applications with only one CMS are not discussed. However, discussion to resolve any points of disagreement relating to the AR, draft SPC, PL and labelling is to be encouraged, i.e. via the List V-MRNA.

Representatives of all CMS (including experts where possible) should be available by telephone, fax or e-mail (in addition to Eudramail) between Day 197 and 210 of the procedure.

Virtual product discussion on Day 201/202 (Day 81/82)

Issues of potential serious risk, together with issues concerning the AR-Resp LOQII, SPC, PL and labelling, should be scheduled for virtual discussion by default, on Day 201/202 of the procedure. All issues should be resolved as far as possible during the discussion (See also CMDv/GUI/021 – GUIDANCE Virtual CMDv product discussions).

Representatives of all CMS who raised potential serious risk (PSR) concerns which were not solved by the applicant's answers, should participate in the virtual product discussion and should be able to resolve issues on behalf of their competent authority (see also CMDv/ROP/001). It is strongly recommended that the national expert(s) raising the PSR issues participate(s) in the discussion.

When the representative from the CMS which raised a PSR issue cannot attend the discussion, the RMS and CMDv Secretariat should be informed, if possible at least one working day before the discussion is due to take place. In this case, a contact name and telephone number for the CMS should be provided along with a response report from that CMS.

The RMS should actively co-ordinate the dialogue between the participants and all efforts should be made to resolve outstanding issues.

After the virtual product discussion

The RMS should inform the applicant immediately after the virtual product discussion of the views presented by the MS concerned during the discussion and give guidance on the measures proposed by the CMS and/or RMS to resolve outstanding issues, including amendments to be made to the draft SPC, PL and labelling.

Within 48 hours of the conclusion of the virtual meeting, the RMS should forward a brief summary note of the outcome of the meeting (position of MS and major issues possibly leading to referral) to the List V-CMD and List V-MRNA and copy the CMDv Secretariat.

As soon as possible after the virtual product discussion, the RMS will receive from the applicant a revised draft SPC, PL and labelling with track changes, incorporating all of the agreed changes. The RMS will check this draft SPC, package leaflet and labelling and circulate it to all CMS involved in the procedure, by Day 203 at the latest. If necessary an updated AR is circulated as well. If agreed with the Member State concerned, the applicant can submit draft translations in order to expedite issue of the national authorisations.

If a further modification of the SPC, PL and/or labelling is then still necessary, a new draft of these should be circulated on Day 205 and commented on by Day 208 of the procedure. The CMS should confirm their final position in respect of granting a marketing authorisation by Day 210. All points must be agreed on regarding the SPC, PL and labelling on or before Day 210. Any request for post authorisation commitments must have been put forward to the applicant by 13:00 GMT on day 208 at the latest (see section 4.7).

Day 210 (Day 90)

On Day 210 the procedure is closed preferably at 13:00 GMT. The RMS will circulate an e-mail to all CMS and the applicant indicating the final conclusion of the RMS and the outcome of the procedure.

Where the RMS has provided a positive conclusion and is prepared to grant a marketing authorisation, the following information should be included in the e-mail:

- A list of CMS agreeing or disagreeing with the final conclusion of the RMS
- If all MS concerned are prepared to grant a marketing authorisation - the Common Renewal Date (CRD)
- A list of any agreed commitments (see section 4.7 below)
- Information on the proposed PSUR submission cycle including the data lock point for the first PSUR
- The final SPC, PL and labelling texts (in English)

The following should be attached to the e-mail if available. If this information is not available at the close of the procedure it will be sent in an email within 3 days:

- The finished product specifications (at release and at the end of shelf life)
- Approved manufacturers of the finished product and active substances (if not already included in the assessment report).

Positive RMS conclusion

If all CMS agree to grant a marketing authorisation for the product, MS concerned will proceed nationally to grant a marketing authorisation (see section 4.5). The RMS will update CTS accordingly and upload the final SPC to the system.

If one or more CMS cannot agree to accept the product the matter will be referred to the CMDv for the 60 day referral process (see section 4.4). The reasons for non-acceptance from CMS will be circulated to the RMS, the other CMS and to the applicant (using template CMDv/TEM/2b).

Negative RMS conclusion

If the RMS concludes that the benefit-risk balance of the product is negative, the application will be refused. No referral to the CMDv will follow.

In principle, an application for a marketing authorisation may be withdrawn by the applicant from a CMS at any time during the decentralised procedure. However, during the assessment step II, once a potential serious risk to human or animal health or for the environment has been raised by a CMS, the withdrawal will not prevent referral to CMDv.

3.4. CMDv referral procedure following a positive conclusion by the RMS

If any issues of PSR of any CMS are not solved by Day 210 (Day 90 of Assessment Step II), the CMDv referral procedure will apply as detailed in the CMDv/SOP/001.

At Day 210 the CMS will give detailed reasoning for their disagreement to the RMS, other CMS and the applicant according to the agreed format. The RMS will refer these points of disagreement to the CMDv without delay.

The MS will use their best endeavour to reach an agreement. If agreement is reached during this referral procedure, the RMS closes the procedure and informs the applicant accordingly. The procedure continues with the national step leading to issue of national authorisations. If no agreement is reached within the defined time frame the matter will be referred to CVMP (see 4.8 below).

3.5. National step – granting of the Marketing Authorisation

If a positive outcome is agreed by Member States concerned at the conclusion of the procedure (see section 4), within 5 days the applicant will send high quality national translations of final SPC, PL and labelling to all MS concerned.

National translations will be submitted in accordance with the CMDv template for product information for MRP and DCP. Additional nationally required information in the PL and labelling will be included in the “blue box”. These are published on the CMDv website.

Templates for product information in all languages have been published on the HMA/CMDv website.

Competent authorities should ensure that authorisations are granted within 30 days after the conclusion of the procedure, provided that acceptable translations are submitted in due time (i.e. correct translation of the SPC, PL and labelling in the language(s) of the MS and mock-ups, as required).

A record in the CTS indicating receipt of acceptable translated texts and their acceptability, together with the date of authorisation, should be made by the CMS.

Within 60 days after the procedure has been completed, it is recommended that the applicant shall collect all documentation sent only electronically after Day 70 in a binder or in an updated electronic submission where accepted and send it to all CMS and the RMS as an annex to the

dossier, to ensure that the information with regard to the application is the same in all Member States and to facilitate any repeat use procedures (CMDv/BPG/003).

3.6. RMS Conclusion

The RMS should also prepare the publicly available assessment report in accordance with the CMDv/BPG/010 and CMDv/SOP/006.

3.7. Commitments

In principle commitments should not be requested of the Applicant by competent authorities during the assessment of the application. Any post authorisation commitment, which will be binding for all involved Member States, should be exceptional and must be requested by the RMS on behalf of the CMS. CMS who request such a commitment should provide full justification to the RMS.

Commitments should be made in a written format, an official signed letter from the applicant clearly stating the time limits for the submission of data. Documentation from the applicant relating to completion of commitments must be sent to the RMS and all CMS simultaneously.

The RMS will provide the CMS with an assessment of the documentation by email with details of the timetable for comments.

If time limits are exceeded or data are insufficient, the matter will be brought back to CMDv for discussion.

3.8. Referral to CVMP

If CMDv has not reached agreement at day 60 of the referral procedure, the RMS should notify the EMA/CVMP in the agreed format (using template CMDv/TEM/011a) and include the CMS reasons for disagreement (CMDv/TEM/011b) in the notification.

ANNEX 1 LIST OF RELATED DOCUMENTS

EMA/TIGes/VET	Guideline on e-submission for Veterinary Products
CMDv/ROP/001	CMDv Rules of Procedure
CMDv/SOP/001	Disagreement In Procedures – referral to CMDv
CMDv/SOP/003	Allocation of the MRP/DCP application number
CMDv/SOP/006	Production and Publication of Public Assessment Reports
CMDv/BPG/008	Automatic Validation of Mutual Recognition Procedures
CMDv/BPG/009	Processing of SPC, Labelling and Packaging provided in support of Mutual Recognition and Decentralised Applications
CMDv/BPG/010	Reference Member State
CMDv/GUI/003	Management of e-mail use during procedures and standardisation of Subheadings
CMDv/GUI/006	Guidance for exchange of documentation relating to RVMP between MS
CMDv/GUI/015	CMDv Guidance for CTS Minimum data input
CMDv/GUI/021	Guidance on Virtual CMDv product discussions
CMDv/TEM/001	Template for the consolidated List of Questions (LOQ)
CMDV/TEM/003	Publicly Available Assessment Report for a Veterinary Medicinal Product
CMDv/TEM/006	QRD veterinary product information annotated template (EN and translations)
CMDv/TEM/ 007	Template CMS Comments MRP/DCP
CMDv/TEM/018	Cover letter for new MA application
CMDv/TEM /2a	RMS referral notification to CMDv
CMDv/TEM/ 2b	CMS reason for CMDv referral
CMDv/TEM/11a	RMS Notification to the EMA/CVMP
CMDv/TEM/11b	CMS annex to RMS Notification for art 33(4) referral

ANNEX 2 LIST OF USED ABBREVIATIONS

DCP	Decentralised Procedure
MA	Marketing Authorisation
MS	Member State(s)
MRP	Mutual Recognition Procedure
BPG	Best Practice Guide
RMS	Reference Member State(s)
CMS	Concerned Member State(s)
CMDv	Co-ordination Group for Mutual Recognition and Decentralised Procedures - veterinary
CTS	Communication Tracking System
SPC	Summary of Product Characteristics
PL	Package leaflet
NtA	Notice to Applicants
DAR	Draft Assessment Report
PAR	Preliminary Assessment Report
AR	Assessment Report
LOQ	List Of Questions
ASMF	Active Substance Master File
PSR	Potential Serious Risk to human or animal health or for the environment
Resp	Response
EMA	European Medicines Agency
PSUR	Periodic Safety Update Report
HMA	Heads of Medicines Agencies
CVMP	Committee for Veterinary Medicinal Products
CRD	Common Renewal Date

ANNEX 3 FLOW CHART FOR THE DECENTRALISED PROCEDURE

Pre-procedural step	
Before Day - 14	Applicant discusses the application with RMS RMS will • Allocate procedure number • Create procedure in CTS • Inform CMS of proposed start date • Inform MS who has authorised the ERP that minimum information on the reference product is required. Submission of the dossier to the RMS and CMS
-14 Days	Automatic validation of the application
Assessment step I	
Day 0	RMS starts the procedure Day 30 circulation of MIRP on reference product if any.
Day 70	RMS circulates preliminary AR and drafts of LOQI, SPC, PL and labelling to CMS and applicant
Day 100	CMS send comments to RMS and other CMS
Day 105	RMS forwards LOQI to the applicant and CMS
Clock-off period	Applicant submits response within 3 months, which can be extended by a further 3 months.
Day 106	RMS restarts the procedure following the receipt of a valid response
Assessment step II	
Day 120 (Day 0)	RMS forwards to applicant and CMS Draft AR including an assessment of the applicant's responses to the LOQI, draft LOQII and drafts of SPC, PL and labelling
Day 145 (Day 25)	CMS send comments to RMS and other CMS RMS forward CMS comments to the applicant
Day 150 (Day 30)	RMS circulates LOQII to applicant and CMS If consensus reached, the RMS can close the procedure
Day 170 (Day 50)	Applicant sends response to LOQII to RMS RMS immediately forwards this to CMS
Day 190 (Day70)	RMS circulates assessment of response to LOQII to applicant and CMS
Day 195 (Day 75)	CMS pre CMDv meeting comments
Day 197 (Day 77)	RMS consults CMS to see whether a Vitero conference is necessary the following Monday/Tuesday.
Day 201/202 (Day 81/82)	Virtual product discussion (if required) RMS informs applicant of outcome of discussions immediately after the discussion and circulates a brief summary to the List V-CMD and List V-MRNA and copy the CMDv Secretariat.

Assessment step II continued	
Day 203 (Day 83)	Applicant sends new drafts of SPC, PL and labelling to RMS. Translations may be included if agreed. RMS immediately forwards this to CMS
Day 205 (Day 85)	If necessary, final drafts of SPC, PL and labelling
Day 208 (Day 88)	CMS send final comment to RMS, including requests for commitments by 13:00 at the latest
Day 209 (Day 89)	RMS circulates final SPC, PL and labelling to CMS and applicant
Day 210 (Day 90)	If consensus on a positive RMS AR is reached, the RMS will close the procedure and circulate the CRD, PSUR cycle, final SPC, PL and labelling, final AR, finished product specifications and a list of any agreed commitments. If consensus on a positive RMS AR is not reached, points of disagreement will be referred to CMDv If the RMS AR is negative, the procedure will be closed with a negative outcome and application rejected.
National step	
5 days after close of procedure	Applicant sends high quality translations to all member states concerned and mock-ups (if required).
30 days after close of the procedure	Granting of national MAs (subject to the submission of acceptable translations and, where required, mock-ups) if no referral to the CMDv.
30 days after close of CMDv referral procedure	Granting of national MAs in RMS and all CMSs if positive outcome of CMDv referral (i.e. no onward referral to the CVMP), subject to the submission of acceptable translations and, where required, mock-ups.