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

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WORKPLAN 2013

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1 Introduction

The Coordination group for Mutual recognition and Decentralised procedures (veterinary) is a platform of the countries in the European Economic Area, to examine questions in relation to:

- Matters regarding individual veterinary medicinal products going through the pre- and post-authorisation mutual recognition procedure (MRP) or decentralised procedure (DCP).
- The application of relevant legislation.
- Harmonisation of national requirements and practices.

Focus points for 2013 are:

- Review of the veterinary legislation;
- Transparency initiatives, particularly in the area of access to document requests concerning the dossiers supporting marketing authorisations;
- Continued work on implementation of the variations Regulation (EC) No. 1234/2008,taking into account the amending Regulation (EC) No. 712/2012;
- Improvement of DCP
- Development of a standard validation checklist for new marketing authorisation applications (MAAs);
- Harmonisation of national implementation of commission decisions following article 34 referrals and transfer to MRP of purely national marketing authorisations (MAs) to maintain harmonisation following a referral;
- Liaising with industry, providing a forum for exchange of ideas, views and concerns;
- Continuous review and any necessary update of existing CMDv guidance documents.

The meeting calendar, a list of CMDv working groups and a list of acronyms are provided in annexes I, II and III.

2 Organisational issues

2.1 Meetings

Every month, except for August, a plenary meeting has been scheduled. Working group meetings will be organised based on need. In addition a presidency meeting is scheduled to take place under the Irish Presidency of the European Union in the first half of 2013.

Product discussions will take place primarily via the Adobe connect system of virtual meetings[1] (a change from the previous system of VITERO) but the more challenging product discussions will be brought to the plenary meeting, at the request of Member States. In addition, it has been agreed that if concerns between Member States become apparent during an on-going MRP/DCP that could potentially trigger a referral, the matter may be brought to the CMDv plenary meeting by either the RMS or any CMS.

The improvement of the meeting process to achieve information, recommendations and decisions more rapidly is necessary. The reintroduction of a table of actions and decisions after each meeting will be the first step to indicate to the members where input is requested.

[1] The use of Adobe can also be extended to other *ad hoc* and working group meetings, as appropriate.

2.2 Working groups

Meetings of the following working groups (WG) are planned for 2013:

- CMDv Notice to Applicants WG, chaired by Sweden
- CMDv Legislation WG, chaired by the UK
- EMA/CMDv working group on transparency, chaired by CMDv Chair and EMA secretariat
- CMDv Borderline WG, chaired by Belgium
- CMDv Document management WG, chaired by the Vice-Chair (Ireland in the first half of 2013 during the Irish Presidency)
- CMDv *ad hoc* Validation WG, chaired by France
- CMDv *ad hoc* discussion group on improvement of the DCP

There will also be CMDv participation at the joint EMA/CMDh/CMDv variations subgroup, the CMDh working group on active substance master file procedures and also the CTS working group.

2.3 Participation and sharing work

All members are required to complete an annual declaration of interest statement and to also declare any interests should one arise during a specific meeting.

To promote active participation of all members, rota schemes for tasks will continue to be used and co-ordinators/rapporteurs will be appointed for Q&As. All members will be requested to clarify their position on important issues during meetings.
Furthermore, new representatives to CMDv would be appointed a 'welcome partner' to aid their swift integration to the group.

An observer from Croatia will be invited to the meetings in the first half of 2013.

3 Authorisation procedures

The CMDv will focus on facilitating communication between Member States during the early phases of pre- and post-authorisation procedures in order to reach consensus at the end of the MRP/DCP. The RMS should give a short briefing in the plenary meeting for any ongoing MRP/DCP where there is already serious concern identified so that discussion can start early on, with the benefit of input from all CMDv members. The list of concerns for CMDv referrals under Article 33(1) will be discussed and adopted during the CMDv plenary meetings (where the timetable allows) or by written procedure to engage all CMDv members present.

4 Policy issues

4.1 Harmonisation and Worksharing

In order to help facilitate harmonisation of veterinary medicinal products CMDv:

- Continues to welcome informal work sharing variations until such times as the amending regulation EC 712/12 comes into full effect enabling products authorised on a national only basis to be included within formal variations.

- Encourages communication between NCAs where significant variations to nationally authorised products are received, so that work sharing can be initiated, to maximise resources across the network and to ensure a consistent assessment of supporting data.

- Will work with CVMP on the development of referrals prioritisation criteria.

4.2 Legislative changes

The CMDv legislation working group aims to review and discuss the European Commission's impact assessment and legislative proposals on better regulation of veterinary medicines in preparation for any proposed changes to the Veterinary Directive[2]. The objective is to help mitigate possible differences in Member States interpretations, to provide feedback to the Commission if difficulties are identified and to help CMDv prepare for possible changes. It has been agreed that the CMDv Chair will regularly report to HMA on the activities/findings of this working group.

The CMDv will also consider any implications arising from the revised variation Regulation and medicated feeding stuffs legislation

4.3 Validation

In the beginning of 2012 the CMDv discussed the simplification of procedure for granting a MA in the context of the review of the veterinary pharmaceutical legislation. Several letters were sent to the European Commission in the context of the review of the veterinary pharmaceutical legislation. In one of these letters, it was proposed to introduce standard validation checklists. CMDv also proposed that, given the transparency involved, validation could be undertaken only by the RMS. This should save resources and duplication of effort in the NCAs as well as greatly reducing the incidences of failed or deferred validation to the benefit of the applicant.

The CMDv decided to start the improvement of the validation of MR and DC MA applications before the review of the veterinary Directive. Consequently the CMDv organised a workshop on validation in margins of the informal CMDv meeting in Amsterdam in November 2012, an *ad hoc* working group has been settled in December 2012.

For 2013, the CMDv will develop a standard validation check list together with a guidance document and an updated timetable for the validation phase. The BPG on validation for MR/DC procedures will be reviewed.

4.4 Improvement of MRP-DCP including national phase

CMDv agreed that it was necessary to look at how current authorisation procedures could be improved through practical solutions within the existing legislation. The CMDv *ad hoc* discussion group on improvement of the DCP will discuss possibilities.

In order to harmonise trade names across the EEA, CMDv will consider a procedure for the agreement of a trade name in connection with a MRP/DCP procedure.

Issues that arise in the national phase, where the harmonised product information achieved during MRP/DCP is changed either by the NCA or the MAH on a purely-national basis will be discussed. The possibilities for reducing labelling text provided by the QRD template v.8 will be used and CMDv will facilitate a harmonised approach regarding labelling in Member States.

4.5 Transfer to MRP of purely-national MAs after Article 34 referrals

The CMDv has gained experience in the transfer of purely-nationally authorised products to MR-products[3]. MAHs of products that have been the subject of an Article 34 referral in the past or are currently involved in an Article 34 referral should contact the CMDv via the secretariat to discuss a potential transfer to MR status for these MAs. It is possible for the CMDv to engage in a dialogue with MAHs on any points that could seem to obstruct of a transfer to MR-status e.g. quality-related issues. The CMDv is committed to treating the transfer to MR-status as a 'light' regulatory procedure. CMDv will take over a more

[2] Directive 2001/82/EC as amended by Directive 2004/28/EC

[3] Recommendation for MRP after finalisation of an article 34 referral procedure with a positive EC Decision

active role by contacting the MAHs involved in an Article 34 referral, inviting them to harmonise and transfer to MR status.

4.6 Role of CMDv in implementation of the HMA Strategy Paper II – key topics

Under the key theme 'Further Improving the Operational Efficiency of Medicines Authorisation by the Decentralised and Mutual Recognition Procedures (DCP/MRP)" within the work area "Streamlining and harmonisation" of the HMA Strategy II, CMDv will focus on the following specific targets and practical priority actions:

Strategy objective (29) Regulation of veterinary medicines

- Review of the veterinary legislation – discussing and providing comments on any amendments or drafts proposed by the European Commission to the veterinary legislation.

Strategy objective (32) Clinical trials in animals

- In line with this objective of the HMA strategic plan, CMDv will at first collect information on how clinical trials are undertaken across the network and how they are managed in the Member States.

Strategy objective (33) To gather information on unregulated areas

- Issues with borderline products:
  - Continue to provide recommendations for classification;
  - Identify the different areas of borderline products;
  - Agree on common understandings;
  - Moving from a case-by-case product-based approach towards a consistent decision based on general principles.
  - Favour a genuine internal market by harmonising the classification of so called borderline products.

Strategy objective (39) Making decentralized processes work better.

- Harmonisation and simplification of the validation process as a crucial part during MRP/DCP – CMDv will develop a common approach on the validation process and a standard validation check list. Other possible options will be explored.

- Finalisation of the HMA/EMA guidance on requests for access to the MAA dossier of an authorised VMP - identification of commercially confidential information (CCI) and protected personal data (PPD).

Strategy objective (40) Extending new EU variation regulation provisions to national variations.

- Continued work on implementation of the variations Regulation (1234/2008), particularly with regard to the extension of this Regulation to nationally authorised products – revision of the Variations Best Practice Guides.

4.7 Availability

The availability of authorised and marketed veterinary medicinal products continues to be a problem for all Member States, particularly those with smaller markets. CMDv is committed to reduce the administrative burdens in so far as practically possible whilst maintaining its regulatory responsibilities under the legislation.

To assist in this aim:

- CMDv will encourage the use of multi-lingual packs.
- The RMS should take into account reduced labelling during pre- and post-authorisation procedures, after considering all aspects of the product and ensuring that labelling is sufficient to allow safe use and administration and identification of the product, while at the same time bearing in mind the need to reduce labelling as much as possible to facilitate multilingual packages..
- Share information on specific product gaps within the individual Member States.

- Inform MS in advance of new applications for MAs for ‘not common’ products.

4.8 Question & Answer (Q&A)

With regard to questions received from external parties requiring a formal answer from CMDv, the secretariat will take the initiative to approach a CMDv member based on the nature of the question and the expertise of each member and request that a draft answer is prepared for the following meeting. The objective is to provide a response after the second CMDv meeting following receipt of the question.
In 2013, members are invited to forward regulatory questions identified as ‘critical’, with an aim committed or similar

- to decrease the national handling of questions (decrease workload)
- to achieve harmonised answers / consensus

Questions from industry or Member States will be discussed by the CMDv members and may require input from other sources e.g. the European Commission, HMA or CVMP. In all cases, within the constraints of legislation, the CMDv decisions will take into account the principles of availability of veterinary medicinal products and reducing unnecessary administrative burdens.

4.9 Access to documents

In the area of access to documents, the CMDv is committed to a common approach with the EMA to ensure consistency of release of information throughout the veterinary regulatory network, notwithstanding over-riding national freedom of information legislation which may be in place in the Member States. Work in this area started in 2012 and will continue during 2013. A joint EMA-CMDv working group is identifying those sections of the marketing authorisation application dossier in veterinary Notice to Applicants (NtA) format that would more often than not be considered as contain commercially-confidential data (CCI) or protected personal data (PPD). Comments from veterinary stakeholders that were submitted as part of the consultation process for the equivalent ‘human’ document (for dossiers in CTD-format) will be taken into account by the EMA-CMDv working group. HMA will be kept up to date with the work of this group and there will be a public consultation process before the resulting guidance document on confidential sections of the NtA MAA dossier is finalised.

5 Document management

A document management system is in place to continue promoting the quality, consistency and transparency of decision-making, to ensure a smooth conduct of procedures, to facilitate the access to documents and to respectively define the areas of responsibilities of the Member States and the secretarial support provided by the Agency. As part of continuous self-assessment and process improvement, the secretariat will liaise with the respective rapporteurs in order to review existing documents which may require updating to stay in line with new developments and practices.

5.1 Documents carried over from 2012

- The draft best practice guide (BPG) on informed consent will be finalised in Q1 2013.
- Guidance on duplicate applications in MRP/DCP: work on this partially-drafted guidance will resume when Volume 6A, Chapter 2 of NTA (MRP) is revised and provides a clearer position.

5.2 Update of existing documents

- The BPG-001 on the mutual recognition procedure is under revision and the updated edition will be adopted by the CMDv in Q1 2013.
- The BPG-002 on the decentralised procedure will be updated.

- There is a need to review the existing BPG-008 on automatic validation of applications in the mutual recognition/decentralised procedures, (carried over from 2012 and will take into account the work of the newly-formed working group on validation).

- CMDv/SOP/006 Standard Operational Procedure for Production and Publication of Public Assessment Reports will be reviewed during 2013 (carried over from 2012).

- The Variations Best Practice Guides and SOPs taken into account Commission Regulation (EU) No. 712/2012 amending Regulation (EC) No 1234/2008 will be updated.

5.3 New documents:

Should the need for new documents be identified during the course of CMDv discussions or handling of procedures, a rapporteur and a co-rapporteur would be appointed and the new task assigned based on prioritisation of needs. New documents already identified for 2013 are:

- A CMDv template for the list of concerns during an Article 33(1) CMDv referral procedure will be prepared, to improve the clarity of the questions to be addressed by the applicant (carried over from 2012).

- A new CMDv BPG on the submission of high-quality national translations (based on equivalent CMDh document).

- A standard validation check list for new marketing authorisation applications in MRP and DCP will be prepared.

6 Cooperation

It is important for CMDv to maintain good relationships with other groups for reasons of efficiency, clarity of purpose and transparency. There is often a need to harmonise policies and responses to industry and to obtain scientific or legal advice. The CMDv will therefore maintain contacts with the following groups.

6.1 Heads of Medicines Agencies (HMA)

The CMDv chairperson will continue to report on the work of the CMDv to HMA on a regular basis.

6.2 Committee for Medicinal Products for Veterinary Use (CVMP)

The chair and secretariat take part in the strategic planning group meetings of CVMP to co-ordinate issues of common interest. The chair will also continue to give a verbal monthly briefing to CVMP on the previous month's meeting and on the agenda of the next meeting. The CVMP secretariat will continue to give a monthly report at the CMDv meeting.

The secretariats of the CVMP and CMDv will liaise to facilitate good cooperation. Agendas and minutes of both groups will continue to be exchanged.

The Presidency meetings also provide an opportunity for CMDv and CVMP members to meet and discuss topics of mutual interest.

6.3 Pharmacovigilance Working Party

Liaison with the Pharmacovigilance Working Party (PhVWP-V) will be continued.

6.4 CMDh

In areas of common interest CMDv will share information, seek co-operation and promote co-ordination of positions and public statements with CMDh. Areas of particular common interest next year will be:

- Transparency, including access to documents;
- Variations:
  - Joint EMA/CMDh/CMDv working group on variations
  - Article 5 classification requests for unforeseen variations
- ASMF (joint CMD/EMA/EDQM/CVMP/CHMP/QWP working group);
- Decisions on generics
- Improvement of DCP

The chairpersons of both groups will meet regularly, e.g. in the margins of HMA meetings and all CMD representatives will have the opportunity to meet and discuss common areas of interest via joint virtual meetings. The secretariats of both groups will liaise to facilitate good cooperation. Agendas and minutes of both groups will continue to be exchanged. The CMDh secretariat will continue to report monthly to the CMDv and vice versa.

6.5 Working Group on the Quality Review of Documents (QRD)

The CMDv will continue to liaise closely with the QRD veterinary subgroup, particularly regarding the implementation of the harmonised and updated centralised/MRP/DCP QRD product information template v.8, which came into effect in late 2012.

6.6 Product Index (VMRI)

A new VMRI product index on the HMA web site became operational in 2012. The lay-out and format of the product index has been improved to provide more and better information on all products approved in MRP/DCP and Art 33 referrals. The data available, e.g. SPC and public assessment report will be generated from CTS (Communication and Tracking System). Member States are requested to focus on the correct input of data into CTS. RMSs are invited to attach the SPC, labelling, PIL and public assessment report.

6.7 E-Submission

CMDv will continue to liaise with the EMA's TIGes vet working group to promote a harmonised approach between the Member States and European Medicines Agency. The communication lines and alignment will be improved between NCAs-TIGes vet group and CMDv to discuss the update of dossier requirements. A joint meeting is considered for dossier requirements between members TIGes vet group and CMDv, since not all NCAs have a TIGes member. CMDv will promote the use of the Common European Submission Platform (CESP) by NCAs and industry.

6.8 Representative organisations

Contacts with interested parties, representing the animal health industry, and veterinarians consulting to the animal health industry, will be maintained through meetings held three times a year. The CMDv will also be happy to meet with representative organisation of other stakeholders, such as veterinarians, farmers and other user groups should interest be expressed.

6.9 Homoeopathic Medicinal Products Working Party (HMPWG)

The CMDv will liaise with the Homoeopathic Medicinal Products Working Party (HMPWG). HMPWG acts as a forum for exchange of regulatory and scientific expertise regarding the assessment of homeopathic medicinal products in Europe. HMPWG provides guidance on the assessment of homeopathic medicinal products and on the registration of homeopathic medicinal products. In particular, the regulatory and scientific expertise for homeopathic veterinary medicinal products is included in the mission of HMPWG.

7 The secretariat

The secretariat, provided by the Agency, will conduct its duties as stipulated in agreed procedures, such as organising meetings, preparing minutes and providing administrative and regulatory support.

Annex I Meeting calendar

Meeting dates	Plenary	Interested parties
Thurs 10 Jan	X	
Fri 11 Jan	X	X
Thurs 7 Feb	X	
Fri 8 Feb	X	
Thurs 7 Mar	X	
Fri 8 Mar	X	
Thurs 11 Apr	X	
Fri 12 Apr	X	
Thurs 16 May	X	X
Fri 17 May	X	
Thurs 13 Jun	X	
Fri 14 Jun	X	
Thurs 18 Jul	X	
Fri 19 Jul	X	
Thurs 12 Sep	X	
Fri 13 Sep	X	
Thurs 10 Oct	X	
Fri 11 Oct	X	X*
Thurs 07 Nov	X	
Fri 08 Nov	X	
Thurs 12 Dec	X	
Fri 13 Dec	X	

*To be confirmed

Annex II List of working groups with CMDv involvement

CMDv working groups	Chair
CTS working group (User & Mgmt) CTS: Future of CTS	Germany (BfArM)
CMDv Document management working group	Chaired by Member State holding EU Presidency
CMDv Borderline products working group	Belgium
CMDv Legislation working group	United Kingdom
CMDv Notice to Applicants working group	Sweden
CMDv Packaging and labelling working group	Czech Republic
CMDv Validation *ad hoc* working group	France
CMDv ad hoc discussion group on improvement of the DCP	United Kingdom
Joint EMA/CMDh/CMDv variations subgroup	United Kingdom (CMDv liaison)
Joint CMD/EMA/EDQM/CVMP/CHMP/QWP working group on active substance master file procedures	Austria (human NCA); CMDv member from Austria also acting as CMDv liaison

Annex III List of acronyms

Adobe connect	System of virtual meetings
The Agency	European Medicines Agency
BPG	Best Practice Guide
CMDh	Coordination group for Mutual recognition and Decentralised procedures (human)
CMDv	Coordination group for Mutual recognition and Decentralised procedures (veterinary)
CTS	Communication and Tracking System
CVMP	Committee for Medicinal Products for Veterinary use
DCP	Decentralised Procedure
EMA	European Medicines Agency
HMA	Heads of Medicines Agencies
MA	Marketing Authorisation
MAA	Marketing Authorisation Application
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NtA	Notice to Applicants
PhVWP	Pharmacovigilance Working Party
Q&A	Question and Answer
RMS	Reference Member State
SOP	Standard Operating Procedure
TIGes-v	Telematics Implementation Group E-Submissions
VITERO	Virtual team room = a facility to hold virtual meetings online
VMRI	Veterinary Mutual Recognition Index