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

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WORKPLAN 2014

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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 2014 are:

- Consideration of the potential impacts of the revised legislative proposals;
- Maximising resources across the network to help achieve harmonisation and consistency of approach;
- Introducing efficiencies in processes and procedures;
- Helping to deliver the appropriate elements of the HMA action plan;
- Liaison with industry working together to resolve issues and drive forward improvements
- Consideration of issues submitted by the member states, or by industry (via the website or communication with the Secretariat), for discussion and formal resolution.

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 Italian Presidency of the European Union in the second half of 2014.

Product discussions will take place primarily via the Adobe connect system of virtual meetings[1] 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.

Following the meeting the Chair and Secretariat will circulate a table of actions, completed with deadlines. Formal minutes will be adopted and a bi-monthly Report for Release will be published on the CMDv website.

[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 2014:

- CMDv document management WG, chaired by Ireland
- CMDv validation WG, chaired by France
- CMDv 'Notice to Applicants' WG, chaired by Sweden
- CMDv WG on improvement of MRP/DCP, chaired by the UK
- CMDv borderline WG, chaired by Belgium
- CMDv WG on packaging, chaired by the Czech Republic
- CMDv WG on legislation, chaired by the UK

There will also be CMDv participation at the:

- joint EMA/CMD variations subgroup
- joint CMD/CxMP/EMA/QWP/EDQM working group on active substance master file procedures
- CTS working group

2.3 Participation and sharing work

The current CMDv Chair has given notice that they intend to stand down as Chair as from July 2014. Consequently there will be a formal election to appoint a new CMDv Chair from within its membership at the September meeting.

All members are required to ensure that their curriculum vitae are up to date and to complete an annual declaration of interest statement. Furthermore it is a requirement that participants declare any interests in relation to any agenda point 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.

Any member whose three year term expires during the year will be required to secure re-appointment from their agency or the agency to put forward a new member.

The CMDv paper on working more efficiently, addressing administrative and organisational issues, as well as on standards for an efficient way of communication and working between all involved parties, will be finalised.

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 work sharing variations for products authorised via CP, MRP/DCP and on a purely national basis as proposed by the amending regulation EC 712/12.
- 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.
- CMDv will consider having a harmonised approach in advising authorisation holders when a referral decision is issued and calling for the appropriate variations as well as on implementation of changes to the product literature.

4.2 Legislative changes

During the year, as the legislative proposals come forward from the Commission, CMDv will consider the potential impacts. Member States will be engaging in the formal negotiation process with the Commission; however CMDv can informally, amongst its members, share views and begin to plan for the implementation where there are changes to key principles. Furthermore, areas can be identified within the proposed legislation where additional clarification would be helpful.

4.3 Validation

In 2013, the CMDv intended to improve the validation phase for new marketing authorisation via mutual recognition procedure or decentralised procedure. A report on the pilot phase which took place between July and December 2013 will be prepared at the beginning of 2014. Based on the conclusions, proposals will be made to CMDv.

4.4 Improvement of MRP-DCP including national phase

As the implementation of the revised legislation will be some way off, CMDv will continue to review the mutual recognition and decentralised procedure processes to see what improvements can be implemented within the current legislative framework. This will involve a review of each key stage of the procedures and a consideration of the pros and cons. Other areas discussed within CMDv, for example labelling and the use of templates, will help to inform this drive for improvement.

As part of the CMDv's efforts to improve the functioning of the DCP and to reduce administrative burden and numbers of questions being posed, the CMDv agreed to pilot the use by applicants of a declaration template relating to versions of the detailed descriptions of their pharmacovigilance system (DDPS) which have already been assessed and accepted during previous application procedures. A twelve month pilot phase will commence in January 2014 for new applications using the decentralised application procedure.

In order to improve harmonisation of trade names across the EEA, CMDv will develop a process to agree on the invented name of the product during the MRP/DCP procedure.

CMDv's work on packaging and labelling will continue in 2014 within the designated working group and there will be further discussion with the CMDv's interested parties. The possibility of a more proactive and flexible labelling review, as well as the use of pictograms/abbreviations will be further discussed.

CMDv will initiate a review of certain aspects of the QRDvet template, with the goal to further clarify and simplify.

CMDv is further reflecting on the possibilities to reduce additional national requirements/to review blue-box requirements within the scope of procedures and for facilitation of multilingual packaging if appropriate.

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

CMDv will support HMA in implementing the HMA Strategy paper II. 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" , CMDv will focus on the following specific targets and practical priority actions:

Strategy objective (21) Publication of SPCs

- NCAs are requested to continue with publication of SPCs for authorised products on their national agency websites and/or Eudrapharm.

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 finalise work in collection information on how clinical trials are undertaken across the network and prepare an analysis of the information. The results will be forwarded to the Commission for their information should they wish to better understand the position within the context of the legislative review.

Strategy objective (33) To gather information on unregulated areas

- Issues with borderline products:
  - Continue to provide recommendations for classification;
  - Agree on common understandings;
  - Moving from a case-by-case *product*-based approach towards a consistent decision based on general principles.

Strategy objective (39) Making decentralised processes work better.

- Review of the key stages of the decentralised procedure and mutual recognition procedure to see if improvements and efficiencies can be introduced and to consider other issues with DCP and MRP that might be improved to increase efficiency and effectiveness.

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 (amending Regulation 712/2012).

4.6 Availability

Availability is a key principle that underpins the work of the CMDv and a factor that is considered during its discussions. Areas that contribute indirectly to the availability agenda include harmonisation between Member States on procedures and processes; reduction of duplication and labelling constraints; a drive to reduce unnecessary administrative burden and to have challenge processes in place to ensure that any concerns over products, or

applications for products, are fully justified. It should be noted that as a regulatory group, CMDv operates within the constraints of legislation.

4.7 E-Submission

The CMDv will promote the use of the Common European Submission Platform (CESP) by NCAs and industry.
CMDv will further promote the use of vNeeS as the only e-submission format. Furthermore, the CMDv will consider the technical validation of e-submissions and acceptance criteria.

4.8 Question & Answer (Q&A)

CMDv is strongly recommending that external parties should send general questions to CMDv, rather than to many/all member state separately. With regard to these questions received from external parties requiring a formal answer from CMDv; the secretariat will take the initiative to approach a CMDv member using a rota system and request that a draft answer is prepared for the following meeting. The nature of the question and the expertise of each member should be considered. The objective is to provide a response after the second CMDv meeting following receipt of the question.
CMDv members are invited to forward regulatory questions identified as 'critical', with the objective

- 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 Autogenous vaccines

The CMDv will start work on autogenous vaccines. Work will be done to develop and complete a survey to have a better vision of the practices in the Member states. A working group will be put in place to analyse the results of this survey, to clarify the words "in the same locality" and to explain the concept of epidemiological links between farms, to define good practices regarding the manufacture and control of autogenous vaccines (to elaborate on minimal requirements) and to make proposals regarding pharmacovigilance of autogenous vaccines.

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 2013

- GUI-010 Recommendation on duplicate applications in MRP/DCP
- SOP-001 on referrals to the CMDv

5.2 Update of existing documents

- General update of the CMDv website and especially of the Q&As
- BPG-007 Renewals
- GUI-006 Exchange of documentation relating to a RVMP between RMS

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.

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 continue to 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; often attending HMA meetings in order to provide clarification on the work of the group.

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 jointly 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.

The chairpersons of both groups will meet regularly, e.g. in the margins of HMA 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 with the QRD veterinary subgroup, as needed.

6.6 CTS and Product Index (VMRI)

Member States are requested to focus on the correct input of data into CTS (Communication and Tracking System). RMSs are invited to attach the SPC, labelling, PIL and public assessment report if the data for the product index will be generated from CTS.

6.7 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. These meetings provide opportunities for industry and regulators to discuss areas of concerns, possible improvements and revisions to Best Practice Guides.
In addition a workshop on worksharing is scheduled to take place in June 2014 organised by EMA, CMDv and interested parties.

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.

6.8 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.
A list of contact points for homoeopathic medicinal products should be created.

6.9 The Commission

A representative from the Commission is invited to attend each meeting and to contribute to the discussions as necessary. This representative receives copies of the meeting papers and links are maintained so that they are aware of any potential issues on which CMDv might seek clarification or a formal Commission position.

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 16 Jan	X	X
Fri 17 Jan	X	
Thurs 13 Feb	X	
Fri 14 Feb	X	
Thurs 13 Mar	X	
Fri 14 Mar	X	
Thurs 10 Apr	X	
Fri 11 Apr	X	
Wed 07 May	X	
Thurs 08 May	X	X
Thurs 05 Jun	X	
Fri 06 Jun	X	
Thurs 10 Jul	X	
Fri 11 Jul	X	
Thurs 11 Sep	X	
Fri 12 Sep	X	
Thurs 09 Oct	X	
Fri 10 Oct	X	X
Thurs 06 Nov	X	
Fri 07 Nov	X	
Thurs 11 Dec	X	
Fri 12 Dec	X	

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	Ireland
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 working group	France
CMDv discussion group on improvement of MRP/DCP	United Kingdom
Joint EMA/CMDh/CMDv variations subgroup	---
Joint CMD/EMA/EDQM/CVMP/CHMP/QWP working group on active substance master file procedures	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
RVMP	Reference Veterinary Medicinal Product
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