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

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WORKPLAN 2012

7 Westferry Circus - Canary Wharf - London E14 4HB - United Kingdom

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 2012 are:

- Review of the veterinary legislation;
- 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;
- Continued work on implementation of the variations Regulation (1234/2008), particularly with regard to grouping and worksharing; and any possible extension of this Regulation to nationally authorised products;
- Completion of pilot procedure for harmonisation of summary of product characteristics (SPC) and review of lessons learned;
- Transparency initiatives, particularly in the area of access to document requests concerning the dossiers supporting marketing authorisations;
- Liaising with industry, providing a forum for exchange of ideas, views and concerns;
- Issues with borderline products;
- Review of the potential serious risk guideline;
- 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 II.

2 Organisational issues

2.1 Meetings

Every month, except for August, a plenary meeting has been scheduled. Due to the anticipated disruption caused by the London 2012 Olympics, the July 2012 meeting of the CMDv will be kindly hosted by the Netherlands. Working group meetings will be organised based on need. In addition a Presidency meeting is scheduled to take place under the Danish Presidency of the European Union in the first half of 2012.

Product discussions will take place primarily via the vitero system of virtual meetings[1] but the more challenging product discussions will be brought back to the plenary meeting, at the request of Member States.

Whilst the main discussion on policy issues and questions from industry will continue to be held on Thursday afternoons, the time slot for decision-making on issues requiring extensive discussion will be scheduled on Friday mornings. This provides members with time for reflection and to seek feedback from their agencies where necessary. The objective is that more decisions are taken earlier, preferably at the meeting in which the issue was discussed, thus reducing the number of items deferred for discussion at a future meeting.

[1] The use of vitero 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 2012:

- Packaging and labelling WG, chaired by the Czech Republic
- CMDv Notice to Applicants WG, chaired by Sweden
- Legislation WG, chaired by the UK
- Joint EMA/CMDh/CMDv variations subgroup, co-chaired by CMDv UK member
- Borderline WG, chaired by Belgium
- Document management WG, chaired by Denmark in the first half of 2011 (as Vice-Chair of the CMDv during the Danish Presidency)
- SPC harmonisation WG, chaired by France

There will also be CMDv participation at the CMDh working group on active substance master file procedures and also at the CTS working group. Designated CMDv members participate in the 'CVMP-CMDv task force on referrals and SPC harmonisation'.

There will be increased use of conference tools for CMDv working group meetings during months where there is a difficult schedule e.g. a month where there is both an interested parties meeting and an oral hearing for a CMDv referral. Working group meetings in between the CMDv plenary meetings could also be a possibility to improve the continuity of major CMDv projects.

2.3 Sharing knowledge and work

CMDv members are appointed for a period of 3 years, which is renewable. Each member carries unique knowledge and experience. All CMDv members are encouraged to participate actively in scientific and regulatory discussions in order to promote coherence, exchange of knowledge and to help share the work equitably across the network. CMDv members are empowered to make decisions on behalf of their Agency and Member State.

In order to learn about national agencies' domains of excellence and members' fields of expertise, each member will be invited during one meeting starting in 2012 to introduce their agency and their current work.

Rota schemes for tasks will continue to be used. 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 2012.

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 disagreement identified so that discussion can start early on, with the benefit of input from other CMDv members. The list of concerns for CMDv referrals under Article 33(1) will be discussed and adopted during the CMDv plenary meetings or by written procedure to engage all CMDv members present.

4 Policy issues

4.1 SPC harmonisation

A pilot phase, started in September 2010, will be completed at the early in 2012 as regards the SPC harmonisation phase (plus standardisation of the quality part of the dossier). The next steps will be:

1. Implementation of the changes in the SPC (Type IB variation application) as well as the changes in the quality part of the dossier (Type II variation application);
2. Transfer of the purely-national MAs involved to MRP-status;
3. Administrative repeat-use procedure to authorise the concerned VMPs in those Member States where they are not authorised (increase availability in small markets).

The CMDv has started a review of the pilot phase in November 2011 and will continue in 2012 in order to enhance the performance of this procedure and to facilitate the management of the different phases. The guidance document for the CMDv's SPC harmonisation procedure will be revised.

Subsequently, other candidate products will be invited to join the SPC harmonisation project. Applicants are invited to provide the names of purely-nationally authorised products for which a harmonisation procedure is relevant. Applicants will participate on a voluntary basis. Applicants willing to participate in a harmonisation procedure should contact the CMDv secretariat at the EMA.

The 'CVMP-CMDv task force on referrals and on SPC harmonisation' will continue its work preparing proposals for new ways of achieving SPC harmonisation within the context of the future revision of the veterinary legislation.

4.2 Legislative changes

The mandate for the new CMDv legislation working group was adopted at the September 2010 meeting. It aims to review and discuss the European Commission's consultation report on better regulation of veterinary medicines and resulting impact assessment in preparation for any proposed changes to the Veterinary Directive[2]. The objective is to help mitigate difference 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.

Work is likely to commence once the Commission has drafted initial legislative proposals following its evaluation of the consultation responses and supporting data. The CMDv will also consider any implications arising from the revised variation Regulation, medicated feedingstuffs legislation and residues legislation.

4.3 Transfer to MRP of purely-national MAs after Article 34 (CVMP) referrals

CMDv would like to gain experience in the transfer of purely-nationally authorised products to MR-products. 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 are encouraged to contact the CMDv via the secretariat to discuss a potential transfer to MR status for these MAs.

4.4 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:

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

- The CMDv has set up a working group on borderline products in 2011 to gather information on unregulated and borderline areas for products used in animals and to consider specific cases of borderline products.

- The CMDv is developing a mechanism to achieve voluntary harmonisation of SPCs and to maintain this harmonisation based on the experiences of the pilot procedure. A strategy to implement the harmonised SPC and standardised Part II of the dossier as well as for transfer of the marketing authorisations (MAs) involved to MRP will be prepared.

- The legislation working group, established with the aim of reviewing and providing comments on any amendments proposed by the European Commission to the veterinary legislation in the context of the recent public consultation on better regulation of veterinary medicines, will review and discuss the EC public consultation report and the impact assessment report as well as the Commission proposal, when available.

4.5 Availability

Availability of authorised and marketed veterinary medicinal products continues to be a problem, mainly in the smaller markets. CMDv is committed to reduce the administrative burden of regulatory procedures, due to the implications on the availability of veterinary medicines.
The following actions are proposed:

- Identifying product gaps in Member States – also for emerging diseases, finding out where relevant vaccines are approved;
- Collecting information on how Member States were addressing availability problems on a national basis;
- Encouraging the widespread approval of narrow-spectrum antibiotics that are already authorised somewhere since there is a strong pressure to stop broad-spectrum antibiotic use (especially in companion animals).

4.6 Labelling

In order to decrease the administrative burden to industry, to allow multi-lingual packs and to promote availability of VMPs, Member States, and especially the RMS, should propose a "feasible" labelling text during MRP/DCP, taking into account all aspects of the products.

4.7 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.

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.

4.8 Access to documents

In the area of access to documents, CMDv will aim to have a common approach with the EMA to ensure consistency for applicants throughout the veterinary regulatory network. In order to achieve this, a joint EMA-CMDv working group is identifying those sections of the marketing authorisation application (MAA) dossier in veterinary Notice to Applicants

(NtA) format that contain commercially-confidential data or personal data that must be protected. 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.

4.9 Review of guideline on the definition of potential serious[3] risk

This activity is carried over from the 2010 workplan. The scope of the guideline is to define in which cases a concerned Member State can refuse to recognise a marketing authorisation in a mutual recognition procedure, or a draft assessment report or draft product information from the reference Member State in a decentralised procedure on the basis of a potential serious risk to human or animal health or for the environment. Taking into account experience gained over the past years, CMDv will review the guideline and propose amendments if necessary changes are identified.

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 2011

- The draft best practice guide (BPG) on informed consent was largely finalised in 2011 and comments from the CMDv interested parties were received during a consultation period. The CMDv has requested clarification from the European Commission on several important principles for informed consent applications and this BPG will be finalised once clarifications are received.

- 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 CMDv guidance document with clock-start dates for MRP/DCP from 2010-2013 will be updated to reflect practical issues for the Christmas and New Year period. Any changes will be notified in the monthly CMDv report for release. Clock-start dates for 2014-2015 will be added.

- There is a need to review the existing BPG 008 on automatic validation of applications in the mutual recognition/decentralised procedures, particularly to take into account validation for electronic submissions.

- CMDv/SOP/006 Standard Operational Procedure for Production and Publication of Public Assessment Reports EMEA/CMDv/67204/2006 – will be reviewed during 2012.

[3] Guideline on the definition of a potential serious risk to human or animal health or for the environment in the context of Article 33(1) and (2) of Directive 2001/82/EC — March 2006

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 2012 are:

- The CMDv will take over responsibility from the European Commission in publishing selected national information on the CMDv website. CMDv rapporteurs will take ownership of individual components from Chapter 7 and collect up-to-date information from the Member States.

- CMDv guidance on the national implementation of CVMP recommendations (e.g. additional safety warnings), whereby CMDv would take a leading role in coordinating this implementation.

- 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.

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. 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 CMDv chair, several CMDv members and the CMDv secretary are members of a joint CVMP-CMDv referrals task force.

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

Increased co-operation between the various groups will be a topic during the Danish Presidency meeting.

6.3 Pharmacovigilance working party

Liaison with the pharmacovigilance working party (PhVWP-V) will be continued and terms of cooperation reviewed.

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 (CMDh *ad-hoc* working group);
- Decisions on generics
- Format of website for publishing of ex-Chapter 7 documents
- Direction of the proposed legislative veterinary directive review.

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 Product Index (VMR-I)

A new product index on the HMA web site becomes operational in 2012. The data available, e.g. SPC and public assessment report will be generated from CTS (Communication and Tracking System). The CMDv will monitor the work of reference member states in order to provide these documents.

6.6 E-Submission and national requirements

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.

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. 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 The Working Group on the Quality Review of Documents (QRD)

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

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 support.

Annex I Meeting calendar

Meeting dates	Plenary	Interested parties
Thurs 12 Jan	X	
Fri 13 Jan	X	X
Thurs 9 Feb	X	
Fri 10 Feb	X	
Thurs 8 Mar	X	
Fri 9 Mar	X	
Thurs 12 Apr	X	
Fri 13 Apr	X	
Thurs 10 May	X	
Fri 11 May	X	X
Thurs 14 Jun	X	
Fri 15 Jun	X	
Thurs 12 Jul	X	
Fri 13 Jul	X	
Thurs 13 Sep	X	
Fri 14 Sep	X	
Thurs 11 Oct	X	
Fri 12 Oct	X	X
Thurs 08 Nov	X	
Fri 09 Nov	X	
Thurs 13 Dec	X	
Fri 14 Dec	X	

Annex II List of CMDv working groups

CMDv working groups	Chair
CTS working group (User & Mgmt) CTS: Future of CTS	Germany (BfArM)
Document management working group	Chaired by Member State holding EU Presidency
Borderline products working group	Belgium
Legislation review working group	United Kingdom
NTA working group	Sweden
Packaging and labelling working group	Czech Republic
SPC harmonisation working group	France
Joint EMA/CMDh/CMDv variations subgroup	United Kingdom (Co-Chair)
CMDh working group on active substance master file procedures	Austria (human NCA); CMDv member from Austria also attending

Annex III List of acronyms

AVC	Association of Veterinary Consultants
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
CVMP-WP	CVMP-Working Party
DCP	Decentralised Procedure
DM	Document Management
The Agency	European Medicines Agency
EGGVP	European Group for Generic Veterinary Products
EMA	European Medicines Agency
HMA	Heads of Medicines Agencies
IFAH-Europe	International Federation for Animal Health Europe
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NTA	Notice to Applicants
PhVWP	Pharmacovigilance Working Party
Q&A	Question and Answer
SMP	Standard Management Procedure
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