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

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WORKPLAN 2011

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CONTENTS

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 mutual recognition procedure (MRP) or decentralised procedure (DCP);
- the application of relevant legislation;
- harmonisation of national requirements and practices.

Focus points for 2011 are:

- 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;
- Completion of pilot procedure for harmonisation of summary of product characteristics (SPC);
- Transparency initiatives.

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

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.

Product discussions will take place primarily via the vitero system of virtual meetings[1] but the more challenging product discussions can be brought back to the plenary meeting, at the request of the 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, hopefully at the meeting in which the issue was discussed, thus reducing the number of items deferred for discussion at a future meeting.

Informal meetings may take place under the Hungarian and Polish Presidencies of the European Union during the course of 2011.

Elections for the position of CMDv chairperson will be held at the November meeting.

2.2 Working groups

New working groups planned for 2011 are as follows:

- New legislation working group (mandate adopted in September 2010)
- New working group on borderline products

There will also be CMDv participation at the CMDh *ad hoc* working group on active substance master files (ASMF)

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

Increased use of conference tools for CMDv working groups meetings will be trialled 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 e.g. voluntary SPC harmonisation scheme.

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 to promote coherence, exchange of knowledge and to help share the work equitably across the network.

Rota schemes for tasks will continue to be used. Furthermore, representatives of those countries who most recently joined the EU would be proposed as rapporteurs for any new subject needing input and would be supported by the more experienced members who would act as co-rapporteurs.

An observer from the candidate country, Croatia, will be invited to the meetings in 2011.

2.4 Use of questionnaires

On new subjects where it is necessary to collect the views of CMDv members in order to reach a conclusion, the current practice is for a questionnaire to be circulated amongst members and then the rapporteur for the topic provides an overview of the responses received during the next plenary meeting. However it is quite a labour-intensive process to compile the replies and to continually update the document when subsequent replies come in. Also CMDv members are obliged to spend a significant amount of time replying to and keeping track of the numerous on-going questionnaires. Therefore the possibility of on-line questionnaires will be investigated, which would streamline the collection of information from all Member States and therefore result in a much more efficient process.

3 Authorisation procedures

In 2011, CMDv will cooperate with IFAH-Europe in developing questions for industry and NCAs to answer as part of a more in-depth, ‘perception-based’ review in the first half of the year. CMDv would subsequently examine the findings of this review and contribute to the conclusions.

4 Policy issues

4.1 SPC harmonisation

The pilot procedure will continue, with a view to completion in the first half of 2011. The subsequent steps of standardisation of the critical pharmaceutical characteristics of the products involved across the Concerned Member States, followed by a transfer to MRP status for the purely-national marketing authorisations will be extensively worked on. If successful, CMDv’s procedural guidance for the voluntary SPC harmonisation scheme will then be refined in the light of experience from the pilot procedure and made public.

The success of this initiative depends on the coordination of parallel activities undertaken by the CVMP task force on referrals, close liaison with CVMP and working in collaboration with industry.

4.2 Legislative changes

The mandate for the new CMDv legislation working group was adopted at the September 2010 meeting. In summary, 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 MS 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.

4.3 Implementation of article 34 (CVMP) referrals

CMDv will focus attention on the maintenance of SPC harmonisation achieved by CVMP referrals. There will be active development of CMDv guidance on national implementation of a Commission Decision following a referral and on transfer to MRP status for purely national products. The aim will be to publish documents no later than by the end of the year and to start monitoring the uptake of the procedures by Member States and industry following each subsequent referral.

4.4 Role of CMDv in implementation of the HMA Strategy Paper II

CMDv has suggested focusing its contributions to the implementation of the HMA Strategy Paper II primarily under the main area 'Making decentralised processes work better'. With this objective in mind, CMDv will continue to act as a forum for the discussion of any specific procedural, regulatory or scientific issues affecting the smooth functioning of on-going MRP/DCP applications. A target area is improvement of the functioning of the validation period for applications – specifically the reduction of additional national requirements, as well as the publication on the CMDv website of those national requirements that are mandatory in some Member States. Equally, the national phase following the positive conclusion of an application (i.e. the phase between granting and actual issuing of a Marketing Authorisation, and approval of the final, national product literature) continues to be an area for improvement where CMDv can play an important role.

Initiatives from industry to voluntarily harmonise dossiers and product information (SPC, labelling and package leaflet) by means of worksharing and CMDv's SPC harmonisation scheme will continue to be encouraged and facilitated.

The work of the new working group on borderline products, which will initially collate information on the existing national regulation of such products, as well as initiating cooperation between MS in this area, supports point 5.57 of the HMA Strategy Paper II "to gather information on unregulated areas… and borderline areas".

The new working group on legislation (see section 4.2 of workplan above) is aligned with a main area the HMA Strategy Paper II on 'Regulation of Veterinary Medicines'.

4.5 Availability

Availability of authorised and marketed veterinary medicinal products continues to be a problem, mainly in the smaller markets. In connection with the SPC harmonisation project, CMDv looked specifically into whether new Member States could be added during the phase of the procedure involving transfer to MRP status of the purely national MAs involved. CMDv will continue to explore this option. In connection with national implementation of Commission Decisions following article 34 referrals and transfer to MRP of purely-national marketing authorisations to maintain harmonisation following a referral, CMDv will explore the same.
CMDv is committed to reducing the administrative burden of regulatory procedures, due to the implications on the availability of veterinary medicines.

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

4.6 Labelling / multi-language packaging

One reason for not applying for marketing authorisations, or for not marketing authorised veterinary medicinal products in small member states, appears to be the cost of labelling requirements, which makes the manufacturing of multi-language packages prohibitively expensive. CMDv has already taken significant steps in the direction of harmonised and reduced labelling, and although no specific activities are planned in 2011 regarding product information, CMDv will continue to take into account, in its discussions, opportunities to solve problems related to labelling.

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 (MS) 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 Transparency and communication

4.8.1 Transparency

CMDv will apply a more proactive approach to transparency in the day-to-day functioning of the group. In the area of access to documents, CMDv will aim to have a common approach with the EMA and CMDh to ensure consistency for applicants throughout the regulatory network. Particular attention will be paid to the recent publication of the EMA's access to documents policy. Also, 'human'-driven documents originating from the HMA/EMA group on transparency will require veterinary input and a worksharing exercise is proposed between CMDv and the EMA's vet sector for this task.

4.8.2 Communication

It is recognised that Member States have an ever increasing European dimension to their work, even in relation to products which may be authorised on a purely-national basis. Decisions taken on these products, although local, may have a wider effect. For example a national decision may have a consequential impact on products being used across the network under the prescribing cascade.

CMDv will therefore initiate work on providing greater transparency/communication between Member States on:

- exchanging information on a monthly basis of products which have been suspended or where a suspension has been lifted. An initial list of all suspended products will be provided.
- providing information on products where it is known that they are not appropriate for use as reference products in any application for a generic product;
- feedback on the quality of assessment reports prepared for MRP / DCP;
- major variations to products authorised on a purely-national basis where it is likely that the same variation is to be made across a number of Member States e.g. significant changes to withdrawal periods or the addition of target species. CMDv can then consider the option of informally worksharing such variations so that the assessment is consistent across the network and consequently the chances of differences occurring in assessment are reduced.

This is not an exhaustive list. The aim is to engender an environment of greater communication in order to better exchange relevant information and to facilitate and progress areas of common interest.

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

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.

4.10 Environmental risk assessment (ERA) for older products

CMDv will provide a forum for discussion on the existing national initiatives of Member States regarding the need for environmental risk assessment of active ingredients authorised in older veterinary medicinal products.

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 a 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 2010

In line with the annual review of existing CMDv documents and templates, the majority of documents and related templates were revised in 2010 to reflect current practices and, in particular, the new variations regulation. Drafting of a few documents will be carried over from last year's workplan:

- The BPGs relating to the new variations regulation on article 5 requests for classification of a variation (BPG015), and for grouping of variations (BPG016);
- A final draft revision of the BPG003 on the repeat use procedure was presented to the interested parties and discussion will continue on the comments received.
- The update of the procedure on handling of PSURs (this update can be carried out once the revised Volume 9 of the Notice to Applicants has been finalised and published).

5.2 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 2011 are:

- CMDv Recommendation for MRP after finalisation of an article 34 referral with a positive decision by the European Commission.

[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

- The draft best practice guide (BPG) on informed consent was finalised in October 2010 but further discussion may be required pending comments from the interested parties by the end of the consultation period on 31.12.10.

- Guidance on duplicate applications in MRP/DCP: work on this partially-drafted (in 2010) will resume when Volume 6A, Chapter 2 of NTA (MRP) is revised and provides clearer position.

- 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.

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 to HMA, on a regular basis, the work of the CMDv.

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 an oral report monthly to CVMP about the issues of the past meeting and the agenda of the next meeting. The CVMP secretariat will continue to give an oral report monthly 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.

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;
- Implementation of the variations regulation:
    - Joint EMA/CMDh/CMDv working group on variations
    - Article 5 classification requests for unforeseen variations
- ASMF (CMDh *ad-hoc* working group);
- Generics policy;
- Quality issues;
- Implementation of referral outcomes following commission decision;

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 report monthly to the CMDv and vice versa.

6.5 Product Index (VMR-I)

There is a need to review the functioning of the product index available on the HMA website since the information available to pharmaceutical industries and other stakeholders, such as animal owners and health professionals, in not up to date. CMDv's input will be required for discussions by both CMD groups on a joint human and veterinary product index, integrated with CTS.

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 among the Member States and European Medicines Agency. CMDv will contribute to guidance on the electronic submission of applications drafted by the EMA's TIGes vet working group. Information on the status of the implementation of e-submission by Member States will be collected by CMDv and made public, along with the national requirements for submission of electronic and paper dossiers.

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.

7 The secretariat

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

Annex I Meeting calendar

Meeting dates	Plenary	Interested parties
Thu 13 Jan	X	
Thu 10 Feb	X	
Fri 11 Feb	X	X
Thu 10 Mar	X	
Fri 11 Mar	X	
Thu 7 Apr	X	
Fri 8 Apr	X	
Thu 5 May	X	
Fri 6 May	X	
Thu 9 Jun	X	
Fri 10 Jun	X	
Thu 14 Jul	X	
Fri 15 Jul	X	X to be confirmed
Thu 15 Sep	X	
Fri 16 Sep	X	
Thu 13 Oct	X	
Fri 14 Oct	X	
Thu 10 Nov	X	
Fri 11 Nov	X	
Thu 8 Dec	X	
Fri 9 Dec	X	X to be confirmed

Annex II List of CMDv working groups

CMDv working groups	Chair
CTS working group (User & Mgm) CTS: Future of CTS	Germany
Diluents working group	The Netherlands
Document management working group	Chaired by Member State holding EU Presidency
Borderline products working group	Belgium
Legislation review working group	UK
NTA working group	Finland
Packaging working group	Belgium
SPC harmonisation working group	Denmark
Survey working group	New appointment needed
Variations working group	UK

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
MS	Member State
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