

WORK PLAN 2010

CONTENTS

1	Introduction	3
2	Organisational issues	3
2.1	Meetings	3
2.2	Sharing knowledge and work	4
3	Authorisation procedures	4
4	Policy issues	5
4.1	SPC harmonisation	5
4.2	Legislative changes	5
4.3	Availability	6
4.4	Labelling –multi language packs.....	6
4.5	Question & Answer (Q&A)	6
4.6	Harmonisation of templates for Product Information	6
4.7	Transparency	6
4.8	Pandemic action plan	6
4.9	Notice to Applicants (NtA)	7
5	Document management.....	7
6	Communication & Cooperation	8
6.1	Heads of Medicines Agencies (HMA)	8
6.2	Committee for Medicinal Products for Veterinary Use (CVMP)	8
6.3	Pharmacovigilance working party.....	8
6.4	CMDh.....	8
6.5	CTS-groups	9
6.6	Product Index (VMR-I).....	9
6.7	E-Submission	9
6.8	Representative organisations.....	9
7	The secretariat	10
	Annex I Meeting calendar	11
	Annex II Procedure dates	12
	Annex III List of acronyms	13

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:

- scientific and procedural 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.

The ongoing revision of the Rules of Procedures, which was initially driven by the new variations regulation (1234/2008), is expected to be finalised and ready to enter into force by 1st January 2010. Subject to the final agreed version, some further work may be required to adjust current practices.

The ratified Lisbon treaty could be in force as early as January 2010 and CMDv would welcome any changes that might affect current practices and adjust to it as early as possible.

Focus points for 2010 are:

- implementation of the variations regulation following the publication of the Best Practice Guides for variations in 2009,
- enhancing meeting efficiency,
- updating the product literature template to combine it with centralised procedures,
- Summary of Product Characteristics (SPC) harmonisation,
- along with the transparency initiative.

The meeting calendar, relevant procedure dates and a list of acronyms are provided in the annexes I, II and III.

2 Organisational issues

2.1 Meetings

Every month, except for August, a plenary meeting has been scheduled. Subgroups meetings will be organised based on need.

With the introduction in June 2009 of “vitero” virtual meetings’ system which have since largely replaced the face to face product discussions, its use may be extended to other ad hoc and subgroup meetings, as appropriate.

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.

Two informal meetings are foreseen under the Spanish and Belgian Presidencies of the European Union during the first and latter half of 2010 respectively, provided the system of rotating EU Presidencies is maintained.

2.2 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 knowledge and to help share the work equitably across the network.

Rota schemes for tasks, introduced in 2008 to better spread the work, 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 any of the candidate countries, Croatia, the former Yugoslav Republic of Macedonia and Turkey, may be invited to the meetings should a definite accession date be set.

2.3 Time length for adoption of answers to questions

A system will be put in place in order to shorten the adoption of draft documents in particular with regard to questions received from external parties needing a formal answer from CMDv. As most of the questions are usually received through the CMDv website, 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. This initiative should help to reduce the waiting time for a response.

3 Authorisation procedures

The number of procedures to be finalised in 2010 is considered to have reached a plateau and no further increase in the number of applications is expected.

The Variations Regulation includes a CMDv referral phase for disagreement between Member States on Type II and work-sharing variations. CMDv will be prepared for handling these, using the established 60-day referral process.

The work on improvement and evaluation of existing procedures will be continued following the outcome of the annual CMDv – IFAH-Europe survey as well as other feedback from industry.

One of the original expectations of the EU legislation on MRP and DCP was that CMS will make their judgements based on the RMS assessment report, rather than assessing the applicant's dossier. As part of the work in the HMA Task Force on Availability of Resources at NCAs for MRP and DCP, the opportunities to reduce parallel assessment by CMS will be considered at CMDv.

The 2008 survey report was published in September 2009 and it will be analysed to identify possible areas of improvement in the conduct of procedures if not already tackled during the course of 2009. The main areas identified referred to an increase in generic applications, a high number of minor questions and non serious risk issues leading to referrals.

Following a fit for purpose review carried out in 2009 with regard to the joint CMDv – IFAH-Europe annual survey, CMDv has recommended that an annual survey reporting the statistical elements should continue as it is useful to identify trends on the nature of procedures and products registered. A more complete survey could be implemented every other year in order to provide a more detailed evaluation of the functioning of MRP and DCP.

4 Policy issues

4.1 SPC harmonisation

The SPC subgroup, which was decommissioned in 2006, was revived in 2009 with a new mandate. The possibility of utilising a voluntary, but simplified, SPC harmonisation procedure was investigated. This would involve dialogue between applicants and National Competent Authorities (NCA), the use of variations and conversion of the national products to MRP status. The subgroup also aims to agree a list of potential candidate products eligible for SPC harmonisation. Discussions would continue and the success of this initiative would very much depend on the coordination of parallel activities undertaken by the Agency task force on referrals, working with CVMP and working in collaboration with industry.

4.2 Legislative changes

In 2009 CMDv developed new best practice guides in line with the new Variations Regulation (1234/2008). CMDv will contribute to a successful implementation of the Variations Regulation by its active participation in the different working groups which have been established to fulfil the new requirements; and will further clarify any outstanding issues identified, particularly in relation to grouping, worksharing and annual reports. Preparatory work would also start for the expansion of Regulation 1234/2008 to include authorisations issued on a national only basis.

The developments with the publication in 2009 of Annex I to Directive 2001/82/EC will be monitored and action will be taken where needed.

The CMDv promotes the initiative of the EC to review the pharmaceutical legislation. Enhancement of public and animal health, increasing availability of veterinary medicinal products, improving functioning of the internal market and decreasing the administrative burden as general objectives of this initiative are supported. With regard to the upcoming update of the veterinary legislation, CMDv's contribution to the development of reflection papers and proposals for improvement is expected and will follow discussions undertaken at the HMA task force on improvements to the veterinary pharmaceutical legislation.

4.3 Availability

In 2010 CMDv will look at what incentives may be offered to increase the number of veterinary medicinal products in small member states with a view to increasing the number of applications in these markets and to look for options to simplify application submissions for products already approved in other member states via DCP or MRP. This will be specifically looked into in connection with the SPC harmonisation project, i.e. if new member states can be added to MRP procedures in connection with the transfer from national to EU procedures. Member States will share information on incentives offered nationally to stimulate the submission of new applications.

4.4 Labelling –multi language packs

Problems related to Labelling, which prevent multi language packages and create availability problems is an area where the CMDv will continue working in 2010. The existing Packaging & Labelling subgroup will convene for any necessary discussions on this subject.

4.5 Question & Answer (Q&A)

Questions from industry or 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.

4.6 Harmonisation of templates for Product Information

CMDv will work on combining the template for product information between all licensing procedures with the input of QRD members. Merging the different product information templates for different procedures into a common template aims to achieve better and more consistent product information.

4.7 Transparency

Since 2005 when the new legislation entered into force a number of activities started in relation to the principle of transparency. The Agency/HMA Transparency group worked on joint recommendations to facilitate a common approach to achieve more proactive transparency on agendas and minutes, access to PSURs and decision-making processes. In line with other Agency committees and national requirements, CMDv will also undertake to move towards increased and proactive transparency, thus not excluding any possible changes to the current way minutes and agendas, access to PSURs and decision making processes are conducted.

4.8 Pandemic action plan

An evaluation on the benefits of developing a CMDv action plan in case of a pandemic will be given due attention. The plan would aim to outline a framework for maintenance of core and critical business functions should an outbreak of pandemic influenza occur.

4.9 Notice to Applicants (NtA)

An update of different chapters of the Notice to Applicants, Volume 6B is urgently necessary. This will be discussed in cooperation with CMDh and EC. CMDv will prepare a compilation of the veterinary topics for update/revision with a summary for each and will send it to EC.

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 define the areas of responsibilities of the Member States and the secretarial support provided by the Agency respectively. 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.

In line with the variations regulation, new best practice guides were finalised and existing documents were identified for revision. The work will continue throughout 2010 to bring all documents in line with new practices and based on the experience gained, new needs might be identified.

Existing documents and related templates for revision and inclusion in the document management system:

- SOP001 Disagreement in procedures - Referral to CMDv, to include Art. 13 referral procedures and Variation referrals (associated templates to be revised);
- SOP003 Allocation of the MRP/DCP application number, to reflect the numbering system for grouped variations, worksharing and experience gained under the new variation regulation;
- SOP008 Advice from CMDv on regulatory matters, to review whether in line with the new version of the Rules of Procedures;
- BPG002 Decentralised procedures;
- BPG003 Repeat Use MRP and DCP;
- BPG007 Renewals;
- BPG011 Active substance Master File in the mutual recognition and decentralised procedures and variation procedures for restricted parts;
- BPG013 Contacts with representative organisations;
- BPG014 Procedure on handling of PSUR (MRP/DCP) once Volume 9 is published;
- BPG015 Article 5 – Unforeseen variations, to include Art.5 common eudranet inbox
- GUI009 Actions after CVMP referral opinion (Art. 33)
- GUI017 CMDv - IFAH Europe guideline on questionnaire.

Should the need for new documents be identified during CMDv discussions and handling of procedures, a Rapporteur and a Co-Rapporteur would be appointed and the new task assigned based on prioritisation of needs.

Every three months, the secretariat will contact the Rapporteurs to ensure the required documents are prepared or updated in a timely manner.

Drafting of a few documents would be carried over from last years' work plan as concurrent documents are still waiting for finalisation. These include:

- Informed consent applications in MRP and DCP (depending on practical experience gained for and the publication of the revised Annex I to Directive 2001/82/EC as amended);
- Electronic submission of documents.

The secretariat would review the currently used "guidance" classification in the CMDv document management system taking into consideration the EU and the Agency recommendation on the categorisation of regulatory documents, and propose a simplified classification system. Also, those CMDv guidance documents used to track ongoing activities like Q&As, discussions at the plenary and items published on the reports for release would be reviewed by the secretariat.

CMDv will also continue its deliberations on whether products which are subject of an Article 34 referral (Recommendation after an article 34 referral procedure with a positive decision by the EC) can be converted to MRP status.

6 Communication & 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:

- NtA review;
- Information technology;
 - the CMD website;
 - CTS;
 - Regulatory scientific memory;
 - Product index
- Implementation of the Variations Regulation;
- Generics policy;
- Quality issues;
- Referrals;
- ERA data;
- Transparency.

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 vitero. 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 CTS-groups

CTS faces a great challenge in relation to the implementation of the new variations regulation in particular with changes connected to grouped variations and work sharing procedures.

Two trainings for CMDv members as well as national agencies' staff and the secretariat will be organised in the first term of 2010 to focus on the new numbering system once aligned to the new variations regulation specifications and a separate one on the production of statistics. Refresher trainings will be followed up via vitero.

6.6 Product Index (VMR-I)

The need to inform pharmaceutical industries and other stakeholders, like patient owners and health professionals, will be considered for the requirements' definition of the veterinary product index. CMDv's input will be required in order to define the veterinary fields' specifications in order to develop the product index at the HMA web page.

6.7 E-Submission

CMDv will continue to liaise with the TIGes-v to promote a harmonised approach among the Member States. Submission requirements shall be defined at national level.

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. 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, look after the external communication, preparing minutes and keeping the administration. The secretariat also gives regulatory advice to the group and to individual members and liaises with relevant stakeholders.

Annex I Meeting calendar

Meeting dates	Plenary	Interested parties	Subgroups
Thu 14 Jan	X		X
Fri 15 Jan	X	X	X
Thu 11 Feb	X		X
Fri 12 Feb	X		X
Thu 11 Mar	X		X
Fri 12 Mar	X		X
Thu 15 Apr	X		X
Fri 16 Apr	X		X
Thu 20 May	X		X
Fri 21 May	X	X	X
Thu 17 Jun	X		X
Fri 18 Jun	X		X
Thu 15 Jul	X		X
Fri 16 Jul	X		X
Thu 16 Sep	X		X
Fri 17 Sep	X		X
Thu 14 Oct	X		X
Fri 15 Oct	X	X	X
Thu 11 Nov	X		X
Fri 12 Nov	X		X
Thu 09 Dec	X		X
Fri 10 Dec	X		X

Annex II Procedure dates

Start date (Day 0)	Day 25 (145 DCP)	Day 54 (MRP)	CMDv ¹	Day 90
29-Oct-2009	23-Nov-2009	22-Dec-2009	15-Jan-2010	27-Jan-2010
26-Nov-2009	21-Dec-2009	19-Jan-2010	12-Feb-2010	24-Feb-2010
23-Dec-2009	16-Jan-2010	14-Feb-2010	12-Mar-2010	23-Mar-2010
28-Jan-2010	22Feb-2010	23-Mar-2010	16-Apr-2010	28-Apr-2010
4-Feb-2010	29-Mar-2010	27-Apr-2010	21-May-2010	2 June 2010
1-Apr-2010	26-Apr-2010	25-May-2010	18-Jun-2010	30-Jun-2010
29-Apr-2010	24-May-2010	22-Jun-2010	16-Jul-2010	28-Jul-2010
1-Jul-2010	26-Jul-2010	24-Aug-2010	17-Sep-2010	29-Sep-2010
29-Jul-2010	23-Aug-2010	21-Sep-2010	15-Oct-2010	27-Oct-2010
26-Aug-2010	20-Sep-2010	19-Oct-2010	12-Nov-2010	24-Nov-2010
23-Sep-2010	18-Oct-2010	16-Nov-2010	10-Dec-2010	22-Dec-2010
28-Oct-2010	22-Nov-2010	21-Dec-2010	14-Jan-2011	26-Jan-2011
25-Nov-2010	20-Dec-2010	18-Jan-2011	11-Feb-2011	23-Feb-2011
23-Dec-2010	15-Jan-2011	13-Feb-2011	11-Mar-2011	23-Mar-2011

¹ Product discussions take place either on the Friday or Monday immediately following the CMDv meeting date, via a Virtual Team Room (VITERO) meeting.

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	De-Centralised Procedure
DM	Document Management
The Agency	European Medicines Agency
EGGVP	European Group for Generic Veterinary Products
HMA	Heads of Medicines Agencies
IFAH-Europe	International Federation for Animal Health Europe
MRP	Mutual Recognition Procedure
MS	Member State
NCA	National Competent Authority
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
VMRI	Veterinary Mutual Recognition Index