

WORK PLAN 2008

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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:

- Scientific and procedural matters regarding individual products going through the mutual recognition procedure (MRP) or decentralised procedure (DCP);
- The application of relevant legislation;
- Harmonisation of national requirements and practices.

CMD(v) aims to further improve the conduct of MRP and DCP in 2008, as well as the functioning of the group, for which actions are set out in the following chapters. Focus points in 2008 are speed of decision making, participation, communication, and use of management tools.

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

2 Organisational issues

2.1 Meetings

Every month, except for the month of August, a regular meeting has been scheduled in accordance with the timetable for MRP and DCP. Subgroup and ad hoc group meetings will be catered for on demand, as experience has taught that a degree of flexibility is required in planning the meetings.

The format of the meeting remains mainly the same as in previous years:

- Thursday morning: subgroups
- Thursday afternoon: plenary
- Friday first half of the morning: plenary, stakeholders meetings or product discussion, depending on the number of ongoing procedures.
- Friday second half of the morning and afternoon: product discussion.

Informal meetings can be arranged at the initiative of the Presidencies of the European Union, being Slovenia in the first half of 2008 and France in the second half.

2.2 Decision making

Preparing responses to new questions from industry or member states often requires a considerable effort. Members have to consider the matter and establish or verify their national position. Sometimes the advice of third parties such as the European Commission needs to be obtained. The views have to be collated and analysed and in case of divergences the possibility for harmonisation will be investigated. All together it may take several months before answers can be delivered. CMD(v) aims to prevent unnecessary delays and to reduce the response time by:

- Appointing a 'project co-ordinator' per Q&A;
- Defining deliverables;
- Establishing and adhering to timetables;
- Considering no-response as agreement;
- Making more use of the possibility to vote where consensus cannot be reached.

2.3 Participation

Each CMD(v) member carries unique knowledge and experience. To make better use of the available expertise and resources, as well as to promote the personal development of the members, the active participation of all members will be promoted by:

- Introducing a rotation system for the allocation of tasks (e.g. preparing answers to questions);
- Requesting all members to clarify their position on important issues during meetings;
- Distributing speaking time more equally;
- Allocating welcome partners to new members;
- Requesting heads of agencies to ensure representation at each meeting and to allocate sufficient human resources.

2.4 Membership renewal and chair elections

CMD(v) members are nominated for a period of 3 years, which is renewable. From 30 October 2008 onwards the first renewals or new nominations are due. Also when a member leaves within the 3 years period a new nomination has to be submitted.

The Member States are responsible for sending in renewals or new nominations in time. The secretariat provides support by keeping track of the expiry dates and by reminding Member States to submit new nominations.

The term for the chairperson is also a period of 3 years and is renewable once. Elections for the position of chairperson will be held at the November meeting or anytime earlier should the sitting chair not complete her term.

3 **Authorisation procedures**

The estimated number of procedures for products for 2008 is stated in the table below. For one product more than one procedure can be conducted due to different strengths or diluents.

MRPs reaching day 90	DCPs reaching day 210	Art. 33 Referrals starting
120 (90 products)	35 (30 products)	8 products (4 to CVMP)

3.1 MRP, DCP and referrals

The MRP is expected to remain an attractive route to expand marketing authorisations for existing products in the European Economic Area. The DCP is, however, enjoying a growing popularity and becoming first choice for new products which are not obliged to go through the centralised procedure. In the past years generic products have increased their share in the total of applications and this trend is expected to continue.

Agencies have been gaining experience and due to the expansion of the EU, more Member States than before may take the role of RMS. Where requested, guidance can be provided by an experienced RMS.

CMD(v) will continue its efforts to prevent referrals. Precedents as set by previous procedures as well as the outcome of discussions on general issues, such as the requirements for generic applications (see 4.1), will be retained as valuable information to prevent or resolve issues. The growing share of generic applications may lead to an increase in community interest and divergent opinion referrals for the reference products to CVMP, considering that efficacy and safety concerns normally cannot be addressed in the framework of a generic application.

These efforts to prevent referrals are without prejudice to the need for addressing genuine issues of potential serious risk to human or animal health or to the environment.

3.2 Survey

The 'traditional' CMD(v) - IFAH-Europe survey will be carried out. EGGVP and AVC will also be asked to contribute.

The areas for improvement identified by the industry during survey 2006 will be taken forward and investigated further in the course of 2008. These include:

- the number and quality of questions asked;
- the CMD(v) breakout sessions;
- the 60-day referral procedures.

The 2007 survey report will be published in the first half of 2008 and it will be analysed to identify possible areas of improvement in the conduct of procedures. Due to the timing of the report any identified improvements will, however, be carried out during the later part of the year and the early part of 2009.

CMD(v) will review with the interested parties the questions in the survey for 2008 to establish which information is required for management and policy development.

A survey on referrals to CMD(v) and from CMD(v) to CVMP will be conducted in conjunction with CVMP. EMEA and IFAH-Europe will lead on this task with assistance provided by CMD(v) as appropriate.

4 Policy issues

4.1 Generics

CMD(v) will provide Member States and industry with guidance on the conduct of MRP and DCP for generic products, in particular with regard to:

- the application of the European reference product;
- situations in which target species, indications or withdrawal periods of the reference product vary among the Concerned Member States.

Thus the outcome of generic applications should become more predictable for industry. In the meantime consideration will be given to the potential impact of generic applications on the reference product.

The guidance will be laid down in a guidance document, taking into consideration advice from the European Commission, the Heads of Medicines Agencies as well as CVMP's opinions on products referred in 2007.

4.2 Packaging

Following a workshop with industry in Prague in spring 2006, CMD(v) has investigated current practices regarding packaging information. The result indicated different approaches among the Member States. After IFAH-Europe indicated its priorities for change, CMD(v) further investigated the opportunities in 2007. In the beginning of 2008 a report with recommendations will be presented to all stakeholders. Where there will be actions for CMD(v) itself, these will be implemented.

4.3 Validation

Applicants report on a regular basis issues regarding validation requirements. Although validation is the responsibility of each individual Member State, the CMD(v) will prepare a question and answer document on recurring validation issues, including additional national requirements. In the framework of this document matters arising from intellectual property legislation will also be investigated.

The work done on validation by CMD(h) in 2007 will be used as a start.

4.4 Variation regulation and revision of Annex I

The planned changes to the variation regulation will require procedures and best practice guides to be updated. Depending on the final text of the amended regulation, significant changes may include the possibility to discuss variation procedures at CMD(v) meetings and the conduct of referral procedures in case of disagreement. CMD(v) will be alert and anticipate to have its (adapted) procedures in place in time.

Likewise the developments with the revision of Annex I to Directive 2001/82/EC will be monitored and anticipated where needed.

5 Document management

A document management system is in place to promote the quality and consistency of decision making, to ensure a smooth conduct of procedures and to define the secretarial support provided by the European Medicines Agency (EMA). The development of only a few new documents is outstanding. As part of a continuous process improvement, some of the existing documents will require revision to stay in line with new insights and practices.

5.1 Documents to be developed

- Procedure to be followed for the request of an Interpretation of a Guideline;
- Maintenance of the CMD(v) website;
- Informed consent applications in MRP and DCP;
- CMD(v)-IFAH Questionnaires;
- Criteria for additional Renewal;
- Electronic submission of documents (TIGes);
- Validation of procedures.

5.2 Documents to be revised

In the 1st quarter 2008 a list of documents to be revised will be drawn up.

6 Communication

CMD(v) recognises the importance of internal and external communication in the functioning of MRP and DCP. The better all stakeholders are informed, the less likely are things to go wrong. Therefore the quality and timeliness of communication will be improved.

Areas for improvement in the external communication include:

- Report for release: faster publication after each meeting. The goal is within 5 working days.
- CMD(v) website: make and keep it up-to-date and tidy. The secretariat will assume the role of web editor.
- Publication of SPCs: the available SPCs on the internet should become complete and represent the valid version.
- Transparency: the release of information will be reviewed in connection with CMD(h).

Regarding the improvement of communication between the member states and to deliver better management information, CMD(v) will investigate which tools should be further developed or used. Existing systems CTS (tracking system for procedures), Eudrapharm (product information), MMD (meeting management of documents) will be considered. The purpose and need for a regulatory and scientific memory database, as mentioned in the CMD(v) rules of procedure will be investigated. Depending on the outcome a development project may be initiated.

CMD(v) will continue communicating with other groups and organisations, as mentioned in the following chapters.

7 Sub and ad hoc groups

The document subgroup is responsible for achieving the targets set out in chapter 5. Considering that the document management system is almost complete and that future activities mainly relate to maintenance, the number of meetings will be scaled down to once in 2 months on average. The survey subgroup will continue to meet when necessary.

In 2006/2007 temporary ad hoc groups have been established, to prepare solutions for issues that require more time than can be allocated during the CMD(v) plenary sessions. Where needed, new ad hoc groups can be established.

The ad hoc group for packaging is to continue its work in the first half of the year.

8 Co-operation with other groups

The relation with other groups is important to harmonise policies and responses to industry and to obtain scientific or legal advice. CMD(v) will maintain contacts with the following groups.

8.1 Heads of Medicines Agencies

The CMD(v) chairperson will continue to report on a regular basis to HMA on the work of the CMD(v). On policy decisions for which CMD(v) requires endorsement of HMA, the heads will be requested:

- to provide clear written responses within reasonable timeframe;
- to ensure good communication between the CMD(v) members and their respective head of agency on decisions relevant to the group.

8.2 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 CMD(v) meeting.

The secretariats of the CVMP and CMD(v) liaise to facilitate a good cooperation. Agenda's and minutes of both groups will continue to be exchanged.

The co-operation with the pharmacovigilance working party (PhVWP-V) will be continued based on a guidance document to be agreed on co-operation and communication.

CMD(v) members will contribute at request to the work of the environmental risk assessment working party, in particular for the development of guidelines. Also on general policy issues and with regard to product/procedure related matters the cooperation will be continued.

8.3 CMD(h)

In areas of common interest CMD(v) will share information, seek co-operation and promote co-ordination of positions and public statements with CMD(h). Areas of particular common interest are:

- Information technology;
 - the CMD website;
 - CTS;
 - Regulatory scientific memory database;
- Generics policy;
- Changes to the Rules of Procedure.

The chairpersons of both groups will meet regularly, e.g. in the margins of HMA meetings. The secretariats of both groups liaise to facilitate a good cooperation. Agendas and minutes of both groups will continue to be exchanged. The CMD(h) secretariat will report monthly to the CMD(v) and vice versa.

8.4 CTS-groups

CTS is the backbone for the tracking of MRP and DCP and also has potential to be further developed as a database for information on products and procedures and as

a source for statistical information. CMD(v) will actively promote its further development in the CTS groups and at HMA.

8.5 TIGes-v

The opportunities of electronic submission are discussed among Member States and with industry in the EMEA TIGes-v group. CMD(v) will continue to liaise with the TIGes-v to promote a harmonised approach among the Member States.

8.6 Representative organisations

Contacts with IFAH-Europe, EGGVP, representing the animal health industry and AVC representing veterinarians consulting to the animal health industry, will be maintained through quarterly meetings.

9 The secretariat

The secretariat, provided by EMEA, will conduct its duties as stipulated in SMP002. In particular the secretariat aims to:

- Continue its support to the main CMD(v) meetings, the document management group and packaging ad hoc subgroup. Secretarial support to other sub or ad hoc groups shall be decided by EMEA on a case by case basis as the need arises.
- Lay down its working practices in an official EMEA Work Instruction.
- Support the investigation of the need for a regulatory and scientific memory database.
- Shorten the time span between each CMD(v) meeting and the publication of the report for release to maximum 5 working days.
- Investigate and stimulate the future development (2009) of EMEA's Meeting Documents System into an interactive tool for CMD(v). The aimed key feature is that meeting agenda's documents are available on-line and editable to the Members, whilst keeping version control. Potentially the system has major efficiency gains.

Annex I Meeting calendar

Meeting Dates	Plenary	Interested parties	Subgroups
Thu 17 Jan	13.00-19.00		08.30-12.00
Fri 18 Jan		09.30-10.30	
Thu 14 Feb	13.00-19.00		08.30-12.00
Fri 15 Feb			
Thu 13 Mar	13.00-19.00		08.30-12.00
Fri 14 Mar			
Thu 17 Apr	13.00-19.00		08.30-12.00
Fri 18 Apr			
Thu 15 May	13.00-19.00		08.30-12.00
Fri 16 May		08.15-09.45	
Thu 19 Jun	13.00-19.00		08.30-12.00
Fri 20 Jun			
Thu 17 Jul	13.00-19.00		08.30-12.00
Fri 18 Jul			
Thu 18 Sept	13.00-19.00		08.30-12.00
Fri 19 Sept			
Thu 16 Oct	13.00-19.00		08.30-12.00
Fri 17 Oct		08.15-09.45	
Thu 13 Nov	13.00-19.00		08.30-12.00
Fri 14 Nov			
Thu 11 Dec	13.00-18.00		08.30-12.00
Fri 12 Dec			

An informal meeting is scheduled under the Slovenian presidency on 26-27 May 2008.

Annex II Procedure dates

Start date (Day 0)	Day 25 (145 DCP)	Day 54 (MRP)	CMD(v)	Day 90
26-Oct-2007	20-Nov-2007	19-Dec-2007	18-Jan-2008	24-Jan-2008
1-Nov-2007	26-Nov-2007	25-Dec-2007	18-Jan-2008	30-Jan-2008
23-Nov-2007	18-Dec-2007	16-Jan-2008	15-Feb-2008	21-Feb-2008
29-Nov-2007	24-Dec-2007	22-Jan-2008	15-Feb-2008	27-Feb-2008
27-Dec-2007	21-Jan-2008	19-Feb-2008	14-Mar-2008	26-Mar-2008
31-Jan-2008	25-Feb-2008	25-Mar-2008	18-Apr-2008	30-Apr-2008
28-Feb-2008	24-Mar-2008	22-Apr-2008	16-May-2008	28-May-2008
3-Apr-2008	28-Apr-2008	27-May-2008	20-Jun-2008	2-Jul-2008
1-May-2008	26-May-2008	24-Jun-2008	18-Jul-2008	30-Jul-2008
3-Jul-2008	28-Jul-2008	26-Aug-2008	19-Sep-2008	1-Oct-2008
31-Jul-2008	25-Aug-2008	23-Sep-2008	17-Oct-2008	29-Oct-2008
28-Aug-2008	22-Sep-2008	21-Oct-2008	14-Nov-2008	26-Nov-2008
19-Sep-2008	14-Oct-2008	12-Nov-2008	12-Dec-2008	18-Dec-2008
25-Sep-2008	20-Oct-2008	18-Nov-2008	12-Dec-2008	24-Dec-2008

Annex III List of acronyms

AVC	Association of Veterinary Consultants
BPG	Best Practice Guide
CMD(h)	Coordination group for Mutual recognition and Decentralised procedures (human)
CMD(v)	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
EMEA	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
PhVWP	Pharmacovigilance Working Party
SMP	Standard Management Procedure
RMS	Reference Member State
SOP	Standard Operating Procedure
TIGes-v	Telematics Implementation Group E-Submissions
VMRI	Veterinary Mutual Recognition Index