

WORK PLAN 2009

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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 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 group completed its first 3 year term in October 2008, on which occasion its functioning was evaluated. Results from this evaluation are included in work plan 2009, as well as continuing activities and scheduled work carried forward from work plan 2008.

Focus points in 2009 are: implementation of the variations regulation, meeting efficiency and “old product” harmonisation.

All CMDv members are encouraged to participate actively in scientific and regulatory discussions.

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 plenary meeting has been scheduled. Subgroups meetings will be organised based on need.

The meeting format will be adapted to enable decisions to be taken faster and to enhance the participation. This includes moving from physical to virtual meeting rooms for certain agenda items. In particular for product discussions and subgroup meetings, where different persons from various geographical locations are required for a relatively short period of time (15 minutes – 2 hours), virtual meeting rooms could be used. It is expected that this approach would increase participation of the relevant experts, to reduce travelling costs and to create greater flexibility to the time of the meeting. Once virtual meetings have been conducted successfully in a test phase, it should be discussed how best to make use of this tool in future and to what extent it could replace physical product discussions. Should virtual product discussion operate successfully, CMDv may consider abandoning the recommended start dates for procedures, thus providing more flexibility for applicants and helping national agencies in flattening work peaks.

Whilst the main discussion on policy issues and questions from industry will continue to be held on Thursday afternoons, a new time slot for decision making on outstanding issues will be scheduled on Friday mornings. This provides members 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 Czech Republic and Swedish Presidencies of the European Union, during the first half of 2009 and latter half of 2009, respectively.

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. To make better use of the available expertise, a list containing this information will be established. Rota schemes for tasks, introduced in 2008 to better spread the work, will be more actively used.

The secretariat will develop an introductory training for new members, covering amongst other things, the organisation of meetings, document management and sources of information. A serving CMDv member will be allocated as a welcome partner to new members. They will act as the main contact for the new member and be available to answer questions in relation to the operation of MRP or DCP.

An observer from Croatia may be invited to the meetings should a definite accession date be set.

3 Authorisation procedures

The estimated number of procedures for products for 2009 is stated in the table below in comparison with previous years. In cases where there are different strengths or diluents progressing at the same time, these will be counted one product.

	Finalised products reaching Day 90/210				Products referred to CMDv (of which referred to CVMP)			
	2009	'08	'07	'06	2009	'08	'07	'06
MRP	80	81	76	70	8(5)	9(5)	4(2)	7(6)
DCP	90	70	26	4	9(3)	9(4)	3(2)	1
Total	170	151	102	74	17	18(9)	7(4)	8(6)

Products MRP, DCP and referrals

The Variations Regulation has introduced a CMDv referral phase for disagreement between Member States on Type II and work-sharing variations. CMDv will be prepared for handling these, though very few are expected to come in.

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 signals from industry.

By the end of 2008 EGGVP raised concerns over growing waiting lists in certain Member States for the start of new procedures, and this will be investigated.

The 'traditional' CMDv - 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 2007 and 2008 will be taken forward and investigated further in the course of 2009. These include:

- the number and quality of questions asked;
- the CMDv breakout sessions;
- the 60-day referral procedures.

These areas were reviewed by CMDv during 2008 as part of its normal business. However, these continue to be of a high priority to the industry and should therefore be kept under regular review.

The 2008 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.

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

4 Policy issues

4.1 SPC harmonisation

It is not uncommon that the SPC of a product, authorised in the past through national procedures, is different from Member State to Member State. Applications for generic products bring these differences to the light, which may result in the reference products being referred to CVMP under Article 34 (divergent opinion) or Article 35 (community interest) of the Directive. Such procedures can be time consuming and usually come unexpectedly for the marketing authorisation holder.

It is therefore worthwhile exploring mechanisms of SPC harmonisation without using heavy referral tools and/or to find ways for better planning and prioritising the use of the referral tool. CMDv will therefore investigate the possibility of voluntary SPC harmonisation through work sharing in variations and also reconsider the option of establishing a list of products for which SPC harmonisation is necessary.

The SPC subgroup, which was decommissioned in 2006, may be revived.

4.2 Legislative changes

CMDv will update and develop procedures in line with the new Variations Regulation. Furthermore, CMDv could be requested to provide recommendations on unforeseen variations. A Best Practice Guide has been developed to help facilitate this process within the 45 day time frame. CMDv will contribute to a successful implementation of Variation Regulation by active participation in the different working groups established to fulfil the new requirements.

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

Although a longer term project, CMDv will contribute to the HMA task force on improvements to the veterinary pharmaceutical legislation, as required.

4.3 Biosimilar products

At the request from EGGVP, CMDv will explore the possibilities and potential framework for authorising biosimilar veterinary medicinal products including vaccines. The exact format of the investigation is to be decided, but input from EMEA, CMDh and industry will be requested.

4.4 Packaging

CMDv published conclusions and recommendations on industry proposals for packaging improvement in October 2008. The group will monitor the impact of the recommendations and keep in touch with stakeholders on any follow-up actions to be taken through the packaging subgroup.

4.5 Validation

Industry has reported a number of national validation requirements that in their view result in unnecessary administrative burdens. CMDv has started investigating a list received from IFAH-Europe and this work will be continued in 2009. A new subgroup, for reviewing national validation requirements may be commissioned as priorities allow.

4.6 Question & Answer

Questions from industry or Member States will be discussed by 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.

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 EMEA respectively. As part of a continuous self assessment and process improvement, the secretariat will monitor and liaise with the respective Rapporteurs in order to review existing documents which might require updating to stay in line with new insights and practices.

The main focus for this year is on the implementation of the Variations Regulation, for which some new documents need to be developed and existing ones need revision. The document management subgroup will liaise with the ongoing Variations Regulation subgroup in order to coordinate the finalisation, classification and publication of the documents and templates, as applicable, such as:

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

- Disagreement in procedures - Referral to CMDv;
- Type IA Variations;
- Type IB Variations;
- Type II Variations;
- Application forms for variations.

New requested drafts, taking into consideration that other ones might be identified at a later stage during the implementation phase:

- Application forms for annual updates;
- Application forms for grouped variations;
- Urgent Safety Procedures – Implementation aspects to strengthen collaboration with PhVWP (if necessary);
- Art. 4 guidelines - Input in drafting various categories of guidelines;
- Art. 5 – Template for request for recommendation;
- Art. 20 – Worksharing – (procedure/ guidance documents/ templates).

The finalisation of some guidance documents will be carried over from last year's initial work plan as their finalisation depends on other ongoing concurrent activities:

- 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 (pending conclusions reached by the TIGes working);

The secretariat would review the currently used “guidance” classification in the CMDv document management system taking into consideration the EU and EMEA recommendation on the categorisation of regulatory documents.

In relation to section 2.2 on sharing work and knowledge, a welcome pack for newly nominated CMDv representatives will be assembled and maintained within the scope of document management.

6 Communication & Cooperation

It is important for CMDv to maintain healthy 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

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

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.

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

Regarding general policy issues and product/procedure related matters the current level of cooperation will be continued.

6.3 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 are:

- The Rules of Procedure.
- Information technology;
 - the CMD website;
 - CTS;
 - Regulatory scientific memory;
- Implementation of the Variations Regulation;
- Generics policy;
- Quality issues;
- Referrals.

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 report monthly to the CMDv and vice versa.

6.4 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. CMDv will actively promote its further development in the CTS groups and at HMA.

A CTS training for CMDv members as well as national agencies' staff using the system will be organised.

6.5 TIGes-v

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

6.6 Representative organisations

Contacts with IFAH-Europe and EGGVP, representing the animal health industry, and AVC representing veterinarians consulting to the animal health industry, will be maintained through quarterly meetings. CMDv will also be happy to meet with representative organisation of other stakeholders, such as veterinarians, farmers and other user groups.

7 The secretariat

The secretariat, provided by the EMEA, will conduct its duties as stipulated in agreed procedures, such as organising meetings, preparing minutes and keeping the administration. The secretariat also gives advice to the group and to individual members and liaises with relevant stakeholders. The main out of the ordinary objectives in 2009 are:

- a smooth introduction of virtual meetings;
- development and organisation of introduction training;
- updating the meeting format;
- Investigation of the possibility of making documents available for consultation and editing through a web-based system.

Annex I Meeting calendar

Meeting dates		Plenary	Interested parties	Subgroups
Thu	15 Jan	X	X	X
Fri	16 Jan	X		X
Thu	12 Feb	X		X
Fri	13 Feb	X		X
Thu	12 Mar	X		X
Fri	13 Mar	X		X
Thu	16 Apr	X		X
Fri	17 Apr	X		X
Thu	14 May	X		X
Fri	15 May	X	X	X
Thu	18 Jun	X		X
Fri	19 Jun	X		X
Thu	16 Jul	X		X
Fri	17 Jul	X		X
Thu	17 Sep	X		X
Fri	18 Sep	X		X
Thu	15 Oct	X		X
Fri	16 Oct	X	X	X
Thu	12 Nov	X		X
Fri	13 Nov	X		X
Thu	10 Dec	X		X
Fri	11 Dec	X		X

Annex II Procedure dates

Start date (Day 0)	Day 25 (145 DCP)	Day 54 (MRP)	CMDv	Day 90
30-Oct-2008	24-Nov-2008	23-Dec-2008	16-Jan-2009	28-Jan-2009
27-Nov-2008	22-Dec-2008	20-Jan-2009	13-Feb-2009	25-Feb-2009
23-Dec-2008	17-Jan-2009	15-Feb-2009	13-Mar-2009	23-Mar-2009
29-Jan-2009	23-Feb-2009	24-Mar-2009	17-Apr-2009	29-Apr-2009
26-Feb-2009	23-Mar-2009	21-Apr-2009	15-May-2009	27-May-2009
2-Apr-2009	27-Apr-2009	26-May-2009	19-Jun-2009	1-Jul-2009
30-Apr-2009	25-May-2009	23-Jun-2009	17-Jul-2009	29-Jul-2009
2-Jul-2009	27-Jul-2009	25-Aug-2009	18-Sep-2009	30-Sep-2009
30-Jul-2009	24-Aug-2009	22-Sep-2009	16-Oct-2009	28-Oct-2009
27-Aug-2009	21-Sep-2009	20-Oct-2009	13-Nov-2009	25-Nov-2009
23-Sep-2009	18-Oct-2009	16-Nov-2009	10-Dec-2009	22-Dec-2009
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

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
EMA	European Medicines Agency
EGGP	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