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

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WORKPLAN 2015

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1 Introduction

The Coordination Group for Mutual Recognition and Decentralised Procedures (veterinary) (CMDv) 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.

Summary Focus Points for 2015 are:

- Consideration of the potential impacts of the revised legislative proposals and gaining clarity on areas of uncertainty;

- Maximising resources across the network to help achieve harmonisation and consistency of approach;

- Introducing efficiencies in processes and procedures;

- Liaison with industry stakeholders, working parties and other regulatory bodies; working together to resolve issues and drive forward improvements;

- Consideration of issues submitted by the Member States (MS), or by industry (via the website or communication with the Secretariat), for discussion and formal resolution.

- The appointment of a formal Vice-Chair and developing associated tasks.

- Contributing to the Heads of Medicines Agencies (HMA) objectives as set out in the HMA strategic plan, particularly in the areas of increasing product availability and reduction of burdens.

- Development of a user guide for new e-applications

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

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. In addition, during the second half of 2015, a presidency meeting is scheduled to take place under the Luxembourg Presidency of the European Union.

Product discussions will take place primarily via the Adobe connect system of virtual meetings[1]. At the request of MSs the more challenging product discussions may be brought to the plenary meeting. In addition, it has also been agreed that if concerns between MSs become apparent during an ongoing MRP/DCP that could potentially trigger a referral, the matter may be brought to the CMDv plenary meeting by either the reference member state (RMS) or any concerned member state (CMS).

2.2 Working Groups

Meetings of the working groups (WG) will be arranged as required with typically two or three being held during the course of the monthly CMDv meeting. The working group meetings will be chaired by the appointed person and all are open for CMDv wide attendance.

Working group meetings planned for 2015 include:

- CMDv document management WG, chaired by Latvia during the first half of the year.
- CMDv validation WG, chaired by France
- 'Notice to Applicants' WG, chaired by Sweden
- CMDv WG on improvement of MRP/DCP, chaired by the UK
- CMDv borderline WG, chaired by Belgium
- WG on autogenous vaccines, chaired by France
- Joint Variations Task Force
- WG on packaging and labelling, chaired by the Czech Republic
- WG on legislation, chaired by the UK

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

There will also be CMDv participation at the joint EMA/CMD variations subgroup; joint CMD/CxMP/EMA/QWP/EDQM working group on active substance master file procedures, CTS working group and the e-submissions veterinary harmonisation group.

2.3 Participation and Sharing Work

To help increase the efficiency and effectiveness of the CMDv meetings, CMDv will appoint a Vice-Chair during 2015. Before doing so, the existing Rules of Procedure will need to be adapted and endorsed by HMA and the Commission. A formal appointment exercise is foreseen and is likely to take place during 2015.

To promote active participation of all members, rota schemes for tasks will continue to be used and co-ordinators/rapporteurs will be appointed for Q&As. All members will be requested to clarify their position on important issues during meetings.

3 Key Tasks for 2015

The following is a brief summary of the key tasks on which CMDv will focus its efforts during 2015. This is not an exhaustive list and priorities might be re-evaluated in order for CMDv to adapt to changing circumstances.

3.1 Increasing Availability of Veterinary Medicinal Products

Given the role of CMDv there is little scope for CMDv to contribute directly to product availability. However, this is a key principle that underpins the work of the CMDv and a factor that is considered during its discussions. Areas that contribute indirectly to the 'availability agenda' include harmonisation between MSs on procedures and processes, reduction of duplication of work and addressing labelling constraints. CMDv will aim to reduce unnecessary administrative burdens and to have challenge processes in place to ensure that any concerns over products, or applications for products, are fully justified. It should be noted that as a regulatory group, CMDv must operate within the constraints of legislation.

3.1.1 Autogenous Vaccines

The CMDv has set up a working group reviewing the requirements for autogenous vaccines. This group is comprised of MS experts and a mandate has been agreed. Work will continue during 2015 to further develop common practices in the MSs in cooperation with HMA/TFIL in order to include the proposals from the WG in the negotiations rounds for legislation revision. The objective is to have, within the legislative framework, harmonised requirements and understanding regarding "in the same locality", regarding the concept of epidemiological links between farms, to define good practices regarding the manufacture and control of autogenous vaccines and to make proposals regarding surveillance and use of autogenous vaccines.

3.1.2 Borderline Products

In line with strategy objective 33 of the HMA Strategic Plan, CMDv will provide advice as requested on unregulated areas and issues with borderline products. CMDv will provide recommendations based on the majority view and try to achieve common understandings and definitions within the framework of the available jurisprudence. The objective is for a consistent decision based approach to be in place across the regulatory network, relying on general principles, when NCAs are asked to consider borderline products.

3.2 Efficiencies and Reductions of Administrative Burdens

As an underlying principle CMDv will support HMA in implementing the HMA Strategy paper II regarding the improvement of the Operational Efficiency of Veterinary Medicines Authorisation.

3.2.1 MRP / DCP

The CMDv will focus on facilitating communication between MSs 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 concern identified so that discussion can start early with the benefit of input from all CMDv members. The list of concerns for CMDv referrals under Article 33(1) will be discussed and adopted during the CMDv plenary meetings (where the timetable allows) or by written procedure to engage all CMDv members.

As the implementation of the revised legislation will be some way off, CMDv will review the mutual recognition processes to see what improvements can be implemented within the current legislative framework. This will involve a review of each key stage of the procedures.

These activities will contribute to the strategy objective number 39 (making decentralised processes work better) as set out in the HMA Strategic Plan.

3.2.2 E-submissions and Validation

The industry has identified e-submissions and validation as an area of concern. Whilst it is recognised that improvements have been made by CMDv and also across the network there is still more that can be done. CMDv will continue to work on removing unnecessary burdens and promote the use of the Common European Submission Platform (CESP). CMDv will further promote the use of vNeeS as the only e-submission format and harmonise technical validation requirements. As an aid to applicants, CMDv will develop a user guide for new e-applications.

3.2.3 Variations

In order to help facilitate harmonisation of veterinary medicinal products, CMDv continues to welcome worksharing variations for products authorised via CP, MRP/DCP and on a purely national basis as proposed by the amending regulation 712/2012/EC. CMDv will promote the benefits that variation worksharing offers in terms of a reduction in the duplication of work with a single coordinated assessment. Furthermore, where significant variations to nationally authorised products are received as individual applications by MSs, CMDv will seek to maximise resources across the network by requesting that worksharing is followed. This will also help to ensure a consistent assessment of the supporting data.

In order for the industry to have greater predictability, CMDv, following a commission decision in the framework of a referral will consider the appropriate lapse time from formal amendment of the marketing authorisation to the referral outcomes appearing on the product literature. A general six month default period is usual but this can be shortened in case a potential serious risk issue is identified for human or animal health, or the environment.

3.2.4 Variations Task Force

In liaison with industry a need to set up a small task force comprising of industry and regulators was identified. The purpose of this task force is to share information so that both industry and regulators have a clear understanding of the issues and burdens faced by the respective parties. The task force will also try to identify possible reduction in burdens whilst still operating within the constraints of existing legislation. Six representatives from industry will sit on this task force along with six from the regulatory side. Four of these will be experts and two members from CMDv. During 2015 an initial face to face meeting will take place, followed by the use of virtual meetings.

3.2.5 Labelling

CMDv's work on packaging and labelling will continue in 2015 within the designated working group and there will be close liaison with the CMDv's interested parties. The possibility of a more proactive and flexible labelling review will be discussed, and the use of pictograms/abbreviations can be further elaborated. CMDv will also liaise with QRD over the agreed species pictograms to ensure consistency of approach with the centrally authorised products.

3.2.6 Conversion of Article 34 Referrals to MRP Status

CMDv will continue to promote to industry the benefits of converting purely nationally authorised products which have been subject to SPC harmonisation under Article 34 referral to the mutual recognised status. This will ensure the maintenance of the achieved harmonisation. The positive experiences of the industry should be communicated. The CMDv should appoint a potential RMS and the marketing authorisation holders (MAH) should be approached following the publication of the Commission decision.

3.2.7 MAH transfers:

As a follow-up of the work begun in 2014, CMDv will develop points to facilitate the handling of situations where a marketing authorisation is held by more than one holder in the MSs. This will consider the harmonisation of handling variations and ensure the follow-up of the pharmacovigilance data.

3.2.8 GMP/CEP certificate suspension/withdrawal:

As a follow-up of the work begun in 2014, CMDv will develop points to facilitate the harmonisation of actions taken nationally when GMP non-compliance issues are identified or a certificate is suspended or withdrawn.

3.3 Legislation

During 2015 CMDv will continue to seek clarification from the Commission over its legislative proposals. It should be noted that CMDv has 'no voice' in the formal negotiation process – this is a matter for the Council meetings. However, CMDv can liaise and discuss with the Commission representative(s) the intention of the proposed wording. CMDv can gain a better understanding of the intent of the proposed legislation in order to inform NCAs and MS organisations who are leading on the negotiation process.

As the negotiations develop, and the shape of the legislative proposals becomes clearer, then CMDv can start to plan for the changes it will face, although much of this is likely to take effect during 2016 and 2017.

CMDv, via the Chair, will also have links with the HMA Task Force on legislation. This will help to contribute to HMA strategic objective number 29.

3.4 Communication

CMDv is an integral part of the European Regulatory Network and having effective and timely communications with stakeholders and other areas of the network is essential. The Secretariat in cooperation with the Chair and discussion of CMDv members will produce the minutes from each meeting. These will be for internal purposes only. Furthermore, on a bi-monthly basis the Secretariat will produce a Report for Release covering relevant decisions and giving advice to the industry. Again this is produced in cooperation with the Chair and following discussion with CMDv members.

3.4.1 SPCs

In line with HMA strategic objective number 21, NCAs will continue to strive to publish SPCs on their national agency websites, VMRI and/or Eudrapharm.

3.4.2 Questions and Answers (Q&A)

CMDv will promote the use of the website for the submission of questions, particularly in cases where the same question is being submitted on an individual national basis. Any question received will be discussed by CMDv, with guidance from other network bodies being sought as appropriate. A response will be provided to the questioner. The questioner will be advised by the Secretariat if there will be a delay in responding whilst further guidance is being sought.

Questions from industry or MSs 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.

Where questions are received from external parties requiring a formal answer from CMDv, the Secretariat will take the initiative to approach a CMDv member using a rota system and request that a draft answer is prepared for the following meeting. The nature of the question and the expertise of each member should be considered. The objective is to provide a response after the second CMDv meeting following receipt of the question.

3.4.3 Document Management

A document management system is in place to continue to ensure the quality, consistency and transparency of decision-making and to ensure access to documents. However, during 2014 a need was identified to have better document management and decision retrieval systems in place to have access to and review previous questionnaires, Commission advice and precedents. This will be progressed during 2015. The various Best Practice Guides and Standard Operating Procedures help to facilitate the smooth management of procedures; and to define the areas of responsibilities of the MSs 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.

When an industry facing document is reviewed, comments will be sought from the interested parties prior to the changes being implemented.

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.

4 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. The CMDv will therefore continue to maintain contacts with the following groups.

4.1 Heads of Medicines Agencies (HMA)

The CMDv Chairperson will attend HMA meetings in order to report on the work of the CMDv and to liaise with HMA for endorsement of decisions as appropriate.

4.2 Committee for Medicinal Products for Veterinary Use (CVMP)

The Chair and the 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 CMDv meeting and on the agenda of the next meeting. The CVMP Secretariat will continue to give a monthly report at the CMDv meeting.

During 2015 there will be a review of the interactions between CMDv and CVMP to ensure that effective levels of communication continue to be in place.

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

The Presidency meetings also provide an opportunity for CMDv and CVMP members to meet and jointly discuss topics of mutual interest.

4.3 Pharmacovigilance Working Party

Liaison with the Pharmacovigilance Working Party (PhVWP-V) will be continued.

4.4 CMDh

In areas of common interest CMDv will share information, seek co-operation and promote co-ordination of positions and public statements with CMDh.

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 continue to report monthly to the CMDv and vice versa.

4.5 Working Group on the Quality Review of Documents (QRD)

The CMDv will continue to liaise with the QRD veterinary subgroup, as needed, with a focus on the use of species pictograms, abbreviations in the labelling texts and possible further refinements to the QRD templates.

4.6 CTS and Product Index (VMRI)

MSs are requested to focus on the correct input of data and upload of documents into CTS (Communication and Tracking System). The Veterinary Mutual Recognition Index is populated via CTS.

4.7 Representative Organisations

Contacts with interested parties, representing the animal health industry, and veterinarians will be maintained through meetings held three times a year. These meetings provide opportunities for industry and regulators to discuss areas of concerns, possible improvements and revisions to Best Practice Guides.

The 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.

The Chair and the Secretariat will usually develop the agenda in cooperation with the senior representatives in IFAH-Europe and EGGVP, who represent the industry and will predominantly be aware of issues affecting this major stakeholder. Furthermore, IFAH-Europe and EGGVP will be conduits for helping CMDv to communicate directly with the veterinary pharmaceutical industry.

4.8 Homeopathic Medicinal Products Working Party (HMPWP)

The CMDv will liaise with the Homoeopathic Medicinal Products Working Party. HMPWP acts as a forum for exchange of regulatory and scientific expertise regarding the assessment of homeopathic medicinal products in Europe.

4.9 The Commission

A representative from the Commission is invited to attend each meeting and to contribute to the discussions, as necessary. This representative receives copies of the meeting papers and links are maintained so that they are aware of any potential issues on which CMDv might seek clarification or a formal Commission position.

There is also liaison with the Commission on providing clarity on the new legislative proposals.

5 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 and regulatory support.

Annex I **Meeting Calendar**

2015 Meeting dates

Dates	Plenary	Interested Parties
15th January	✓	
16th January	✓	✓
12th February	✓	
13th February	✓	
12th March	✓	
13th March	✓	
9th April	✓	
10th April	✓	
7th May	✓	
8th May	✓	✓
4th June	✓	
5th June	✓	
9th July	✓	
10th July	✓	
10th September	✓	
11th September	✓	
8th October	✓	
9th October	✓	✓
5th November	✓	
6th November	✓	
10th December	✓	
11th December	✓	

Annex II List of Working Groups with CMDv Involvement

CMDv WG	Chair
CTS WG (User & Mgmt) CTS: Future of CTS	Germany (BfArM)
CMDv document management WG	Latvia (Jan – Jun) -- (Jul – Dec)
CMDv borderline products WG	Belgium
CMDv legislation WG	United Kingdom
CMDv 'Notice to Applicants' WG	Sweden
CMDv packaging and labelling WG	Czech Republic
CMDv WG on autogenous vaccines	France
CMDv validation WG	France
CMDv discussion group on improvement of MRP/DCP	United Kingdom
Joint EMA/CMDh/CMDv variations subgroup	---
Joint CMD/EMA/EDQM/CVMP/CHMP/QWP working group on active substance master file procedures	CMDv member from Austria also acting as CMDv liaison
E-submissions – veterinary harmonisation	Estonia

Annex III **List of Acronyms**

Adobe connect	System of virtual meetings
The Agency	European Medicines Agency
BPG	Best Practice Guide
CESP	Common European Submission Platform
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures (human)
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures (veterinary)
CMS	Concerned Member State
CTS	Communication and Tracking System
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Decentralised Procedure
EMA	European Medicines Agency
HMA	Heads of Medicines Agencies
HMPWP	Homoeopathic Medicinal Products Working Party
MA	Marketing Authorisation
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NtA	Notice to Applicants
PhVWP	Pharmacovigilance Working Party
Q&A	Question and Answer
QRD	Quality Review of Documents
RMS	Reference Member State
RVMP	Reference Veterinary Medicinal Product
SOP	Standard Operating Procedure
VMRI	Veterinary Mutual Recognition Index
WG	Working Group