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

EMA/CMDv/862938/2011
London, 9 February 2012

ANNUAL REPORT 2011

7 Westferry Circus - Canary Wharf - London E14 4HB - United Kingdom

CONTENTS

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;
- The harmonisation of national requirements and practices.

Focus points for 2011 were:

- Development of recommendations for transfer to MRP of purely-national marketing authorisations (MAs) following an article 34 referral procedure, which has led to complete harmonisation of the summary of product characteristics (SPC), in order to maintain the harmonisation achieved by the referral;
- Implementation of the variations Regulation (1234/2008), particularly with regard to grouping and worksharing;
- Development of a mechanism to achieve harmonisation of SPCs and to maintain this harmonisation;
- Establishment of a new working group on borderline products to gather information on unregulated and borderline areas for products used in animals and to consider specific cases of borderline products;
- Discussion of current packaging requirements
- Transparency initiatives, particularly in the area of sharing of information between Member States on specific products.

A list of the referrals to the CMDv finalised in 2011 is provided in Annex I and a list of acronyms are provided in Annex II of this document.

1 Organisational issues

1.1 Members

The vice-chairpersons during the Hungarian and Polish presidencies of the Council of the European Union were Mária Szabó for Hungary and Anna Kucharska for Poland.
The European Commission was represented at the meetings by Martinus Nagtzaam.
Members from Finland and France were replaced during the year.

A full list of members and observers is provided in Annex II. The list of CMDv members, including their professional qualifications, is published on the CMDv website (http://www.hma.eu/cmdv.html).

1.2 Meetings

Under the Hungarian and Polish Presidencies, there were two additional CMDv meetings, both as an individual session and joint with the CVMP.

In Budapest on 30-31 May, the following agenda points were discussed by the CMDv:
- Review of the veterinary legislation by the Commission.
- Experienced gained from the pilot CMDv SPC harmonisation procedure, so far.
- Follow-up on the identification of the European Borderline Assessment Network (for borderline products)
- Report from human-led ad-hoc group on Active Substance Master File assessment.
- Transparency initiatives.
- Availability problems.
- Honeybee health.

In Warsaw on 22 November, the following agenda points were discussed by the CMDv:

- Review of the 'sunset clause' – practical examples from two Member States.
- Overview of the experience gained from the CMDv's pilot SPC harmonisation procedure and feedback from Member States on their views for the future of this initiative.
- Current review of the veterinary legislation – background information from the reports published on the Commission's website and identifiation of the areas of main interest for the CMDv
    - ↳ Discussion on the future of authorisation procedures.
    - ↳ Discussion on options for changes to data protection periods to address availability issues.
- Simplification of packaging and labelling requirements.
- Experience from a Member State of current issues associated with the assessment of the detailed description of the pharmacovigilance system and periodic safety update reports.

Elections of CMDv chairperson in November

On 10 November 2011, Esther Werner of the Paul-Ehrlich-Institut in Germany was unanimously re-elected as the Chair of CMDv for a further three-year term.

1.3 Product discussions

Product discussions in respect of MRP and DCP procedures reaching Day 78 and 198 continued to take place via a client-server based web conferencing software on Mondays and Tuesdays following the plenary sessions. Due to the successful handling of this software, no face-to-face product discussion was requested by any RMS during the plenary meeting, except for those procedures resulting in CMDv referrals and consequent oral explanations by the applicant to the CMDv.

1.4 Working groups

1.4.1 Notice to applicants WG

The main focus was the Commission's update of Chapter one, Volume 2A of the NtA (marketing authorisation), which was being led by the human side but was the precursor to the update of the equivalent veterinary document (NtA Vol. 6A, Chpt 1). The CMDv working group has also started to review and update the information in NtA Volume 6A, Chapter 7 NtA (General Information), for eventual re-publication on the CMDv website.

1.4.2 New legislation WG (mandate adopted in September 2010)

The activities of this working group in 2011 are described in detail in section 4.2.

1.4.3 New WG on borderline products

A new working group was set up with the aim of gathering information on unregulated and borderline areas for products used in animals and to consider specific cases of borderline products. The mandate of the borderline WG was adopted in April 2011, and supported by HMA and EC. Subsequently a European Borderline Assessment Network (EUBAN) was identified and a list of contact points was created. The full overview of the regulatory framework interface for borderline products was compiled.

1.4.4 Packaging/labelling WG

The activities of this working group in 2011 are described in detail in section 4.6.

1.4.5 CVMP-CMDv task force on SPC harmonisation and referrals

A strategic paper was sent to HMA in April 2011. HMA has accepted the proposals from the task force. The first consequence was a change of the name of the task force in order to introduce the SPC harmonisation as a new mandate for this group. Indeed, SPC harmonisation can become an alternative to referral procedures in a more simple and flexible way. The group started to work in October developing proposals for the future

legislation especially for the harmonisation of SPCs of VMPs with purely-national MAs for which disharmonisation exists across Europe.

1.4.6 Variations WG

The CMDv contributed to the Commission's consultation exercise in relation to the amendment of the Variations Regulation (EC) 1234/2008. The CMDv strongly supported the proposal to extend the Variations Regulation to include products authorised on a purely-national basis and also supported the inclusion of purely-nationally authorised products within worksharing procedures. The full CMDv contribution can be viewed on the Commission's website when it is published as part of their consultation process.

Members of the CMDv also actively participated at the two meetings of the EU Variations Task Force in June and July 2011 and at the joint EMA/CMDh/CMDv variations subgroup meetings.

1.4.7 Document management WG

The activities of this working group in 2011 are described in detail in section 5.

1.4.8 CMDv participation at the CMDh ad hoc working group on active substance master files (ASMF)

The joint CHMP/CVMP/CMDh/CMDv working group on ASMF procedures aims at improving and optimising the ASMF assessment procedures by:

- Considering the feasibility of a worksharing procedure for ASMF assessments;
- Developing an EU numbering system for ASMF procedures and a centralised database for all assessment reports of ASMFs.

This should enable the EEA national competent authorities and the EMA to have access to one version of the ASMF for an active substance and to recognise one assessment report for active substances used in Human and Veterinary Medicinal Products.

2 Authorisation procedures

A total of 232 MRP/DCP procedures were finalised, relating to 171 products. Table 1 provides an overview of the number of products that reached the end of the DCP and MRP over the last five years.

Table 1 MRP and DCP products (procedures) finalised

	2011	2010	2009	2008	2007
MRP	72 (89)	42 (57)	50 (57)	79 (84)	76 (88)
DCP	99 (143)	67 (99)	68 (86)	70 (89)	26 (30)
Total	171 (232)	109 (156)	118 (143)	149 (173)	102 (118)

There was approximately a 35% increase in the total number of authorised products compared to the previous year.

The Member States processed the applications within the legal deadlines; those taking on the role of RMS per procedure are shown below in table 2.

Table 2 Number of procedures per Reference Member State

UK	IE	FR	ES	NL	DE	AT	HU	DK	BE	CZ	PT	NO	FI
69	60	28	23	16	16	4	4	3	3	2	2	1	1

2.1.1 Referrals

In total 18 referral procedures were finalised by the CMDv in 2011. Overall the number of referral procedures to the CMDv increased by 60% compared to the previous year and the success rate approximately halved. The graphs below illustrate the statistics and motives for the CMDv referrals started in 2011.

Figure 1

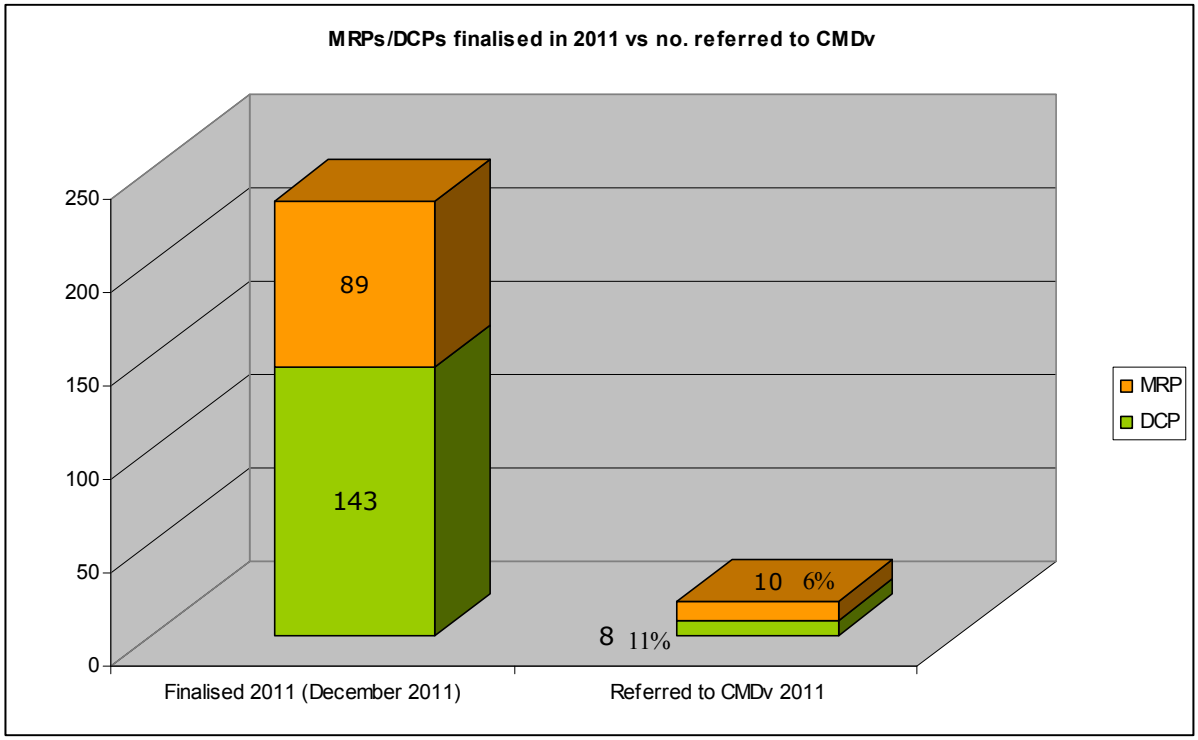


Figure 2

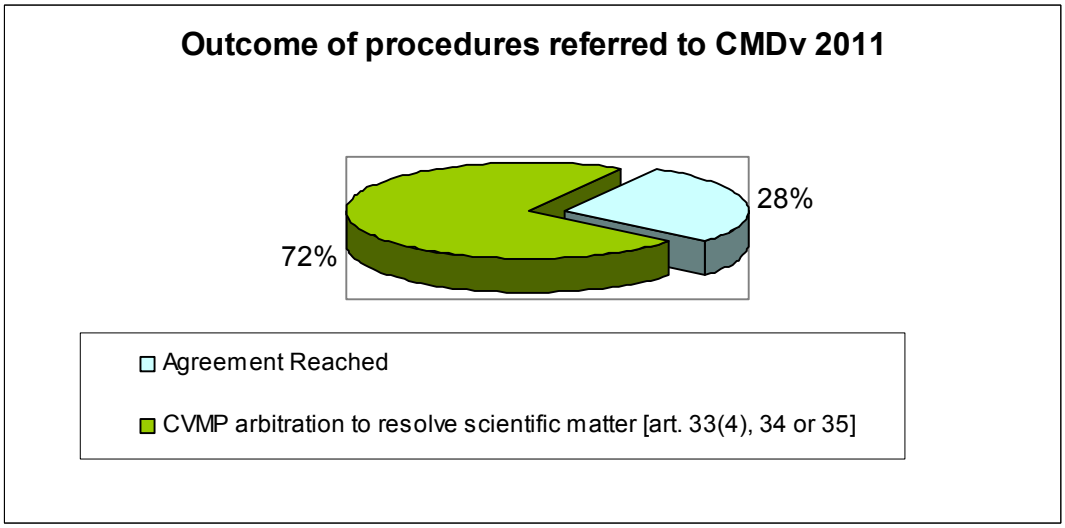


Figure 3

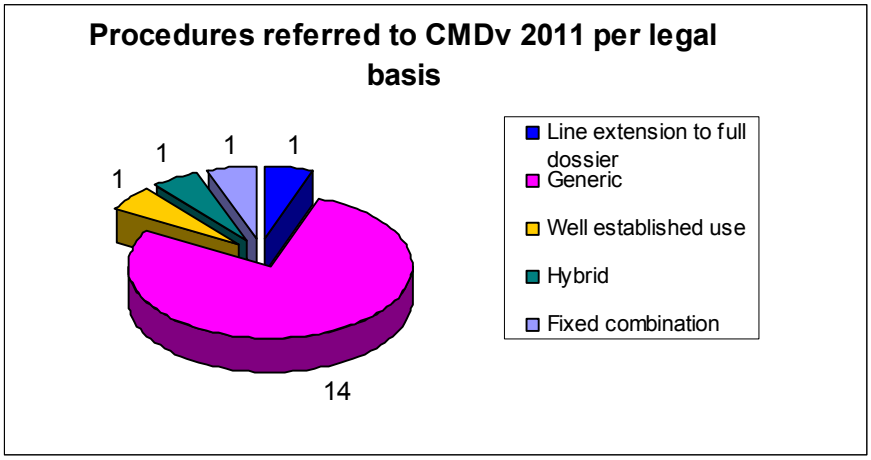


Figure 4 (NB: BEQ = bioequivalence; ERA = environmental risk assessment)

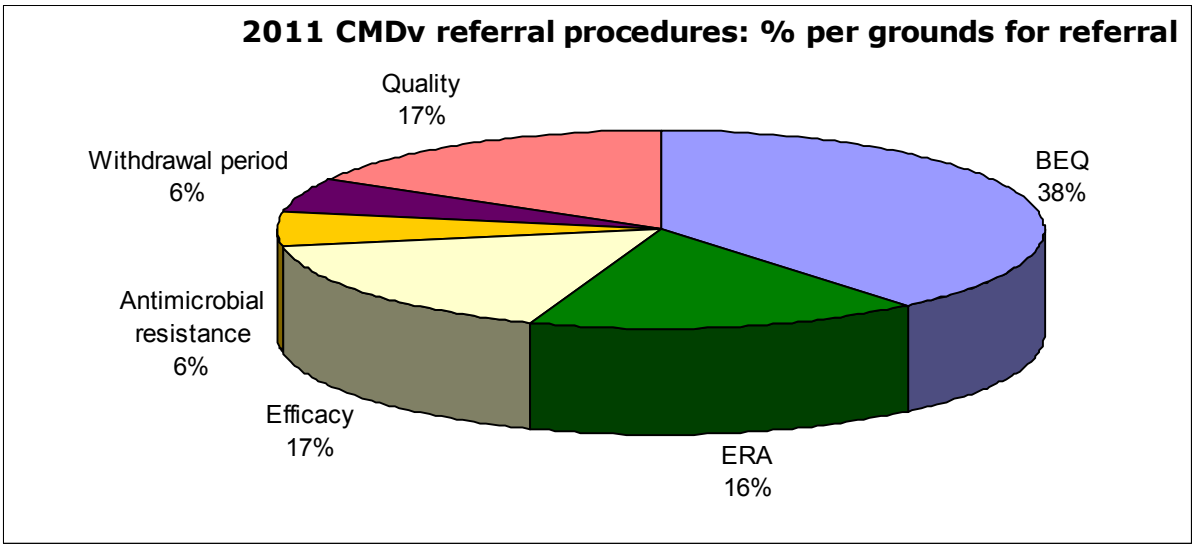
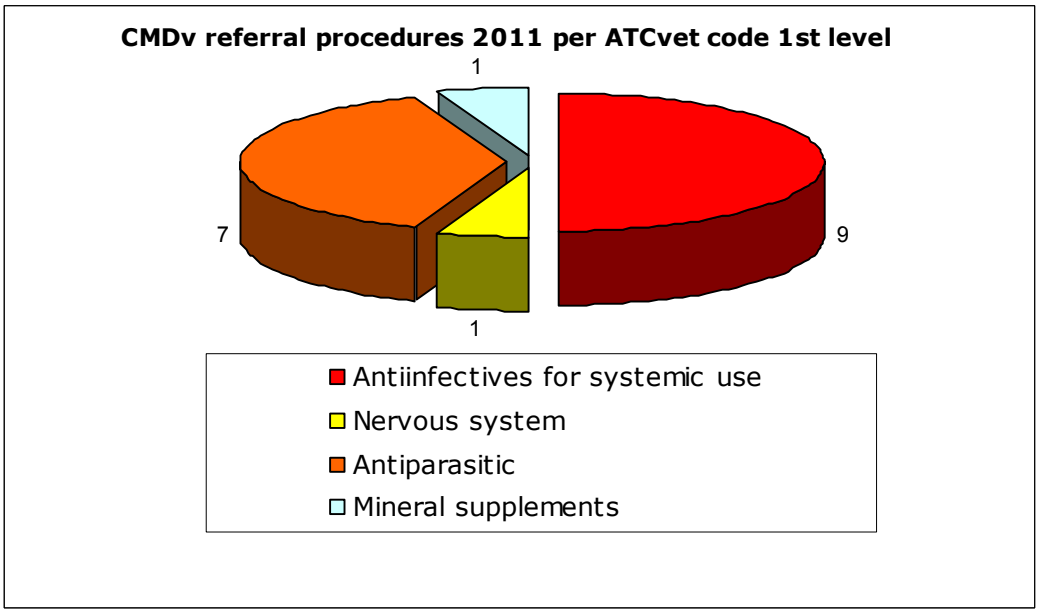


Figure 5



3 Policy issues

3.1 SPC harmonisation

The first part of the year 2011 was dedicated to the definition of the SPC harmonisation procedure. The discussion focused on the objectives of this procedure: to create an alternative to referrals in as flexible and pragmatic procedure as possible. So a timetable was proposed for the SPC harmonisation phase and adopted before the summer break. Another aim of this procedure is to transfer the marketing authorisation from purely-national to European, via a mutual recognition procedure or a repeat-use procedure if the product is not authorised in a Member State where it can be of importance. So availability problems could be solved with this procedure. Transferring the MA in a "European" procedure will facilitate future variations, hence reduce administrative burden for MAH and NCA. To achieve this aim the quality part of the dossier (Part II) also needs to be checked during the SPC harmonisation phase. Since the entirety of Part II cannot be updated during the SPC harmonisation procedure, the RMS should focus only on the standardisation of the critical pharmaceutical characteristics essential for transferring of the MA to MRP-status, as well as for the control of the VMP. Therefore a list of 10 critical points was proposed and accepted for the standardisation of the quality part of the dossier.

The second part of the year was used to test the procedure: a candidate product was identified by the CMDv and the marketing authorisation holder has the great willingness to participate. This veterinary medicinal product was chosen firstly because generic applications were running with difficulty. Indeed, a big disharmonisation was highlighted between the SPCs of the purely-nationally authorised products. This VMP, consisting of three strengths, is authorised for food-producing species, companion and exotic animals in EU/EEA member states since a very long time. The procedure started in September when the MAH send a proposal for SPC.

Then following months were dedicated to the harmonisation itself of the SPC and to the standardisation of the quality part.

3.2 Legislative changes

In preparation for the review of the Veterinary Directive a legislation working group was commissioned by the CMDv in September 2010 under the Chair of the UK. During 2011 this working group largely had a watching brief as the Commission's evidence-gathering processes took place. The CMDv were informed of the findings of the Commission's Impact Assessment via the full reports published on the Commission's website.

A summary on those areas with specific interest to the CMDv was presented by CMDv Members at the Presidency meeting held in Warsaw in November 2011. It was noted that in preparation of the consultant's report, information was sought from national competent authorities on the numbers of marketing authorisation applications, variations and renewals received, how many were issued and in what timeframes. There were also case-studies and in-depth research was carried out in six member states.

The results from the 49 policy options developed can be summarised into eight key areas:

- Data exclusivity,
- Authorisation procedures,
- Packaging and labelling,
- Pharmacovigilance and monitoring,
- The distribution channel,
- Off-label use,
- Harmonisation of existing MAs,
- New needs and challenges.

These areas can be brigaded into three over-arching topics:

- The availability of medicines
- The operation of a single market
- The reduction in administrative burdens

At the November Presidency meeting, and formally endorsed at the CMDv meeting in December, it was agreed that the legislation working group would meeting early in 2012 to discuss initially the authorisation procedures in order to provide further options / proposals for the Commission to consider in its development of any revised legislation.

3.3 Transfer to MRP of purely-national MAs after article 34 (CVMP) referral procedures

The CMDv has drafted guidance on how to proceed after an article 34 referral which has led to complete[1] harmonisation of the SPC. The aim is to maintain the harmonisation achieved following the referral. The document elaborates recommendations on steps to be taken before and after the implementation of Commission Decisions.

A first draft of the document entitled "Recommendation for Mutual Recognition Procedure after finalisation of an article 34 referral procedure with a positive decision by the E.C." was sent to the CMDv interested parties following the February CMDv meeting for consultation. Contributions were received until mid-August and the comments were considered carefully by the CMDv. Finally the document was adopted at the October meeting and published on the CMDv website. During the consultation period a pilot transfer project was started for a product under referral for which a positive CVMP opinion has been given. The transfer took place in June before the EC decision was issued (in July) and the process was successfully finalised in September after implementation of the Commission Decision.

It was confirmed that CMDv would like to continue with these transfers to MR-status and MAHs are therefore encouraged to contact the CMDv secretariat to discuss a potential transfer.

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

CMDv has focussed its contributions to the implementation of the HMA Strategy Paper II primarily under the main area 'Making decentralised processes work better'. The 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. Procedural, regulatory and scientific issues arising from the mutual recognition and decentralised procedures, and also from variation and renewal procedures were permanent items on the monthly CMDv meeting agendas. An intensive, continuous dialogue between Member States took place to ensure smooth functioning of procedures, maintenance of high-quality, robust assessment and achievement of European consensus in MRP and DCP. This was supported by the development and the regular update of procedural guidance documents.

The work of the new working group on borderline products, which initially collated 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 is aligned with a main area the HMA Strategy Paper II on 'Regulation of Veterinary Medicines'.

[1] If the quality (Part II) aspects of the SPC have not been harmonised, it is first necessary to harmonise the 'critical pharmaceutical characteristics' of the product.

3.5 Availability

Availability of authorised and marketed veterinary medicinal products continues to be a problem, mainly in the smaller markets, and one reason, if not the main reason for availability problems in small markets is considered to be labelling requirements. The CMDv has focused on this, for example in connection with the update of the QRDvet template, which took place in 2011, where the CMDv's view was to reduce labelling as much as possible within the frame of current legislation. During MR and DC procedures, CMDv members have encouraged reduced labelling, making multi-lingual packages a feasible option. Additionally, CMDv has explored the possibility whether new Concerned Member States could be added to procedures in an administrative way following transfer of purely-national MAs to MRP-status following article 34 referrals or following voluntary SPC harmonisation. The view of CMDv is that this is possible, based on an agreement between the MA-Holder and the Member State concerned.

3.6 Labelling / multi-language packaging

Discussions on the revision and simplification of packaging/labelling requirements intensified during the course of the year by all stakeholders. An extensive discussion document was presented by Iceland at the CMDv meeting hosted by the Hungarian Presidency on the need for change in connection with the Commission's public consultation on better regulation of VMPs. During the second half of 2012, the Czech Republic acted as rapporteur for this topical issue and chaired several meetings of the reactivated CMDv packaging working group.

A new task for the CMDv packaging working group was agreed at the CMDv October 2011 meeting. The aim was to reconsider the minimum requirements for labelling which present barriers to the availability of VMPs due to the huge cost of meeting current requirements and tailoring labelling to individual markets.

In the latter part of 2011, discussions took place at CMDv and at a workshop hosted by the Polish Presidency in associated with IFAH-Europe with the aim of establishing a harmonised approach among EU Member states on the minimum elements required on the labelling/packaging and how these should be expressed e.g. pictograms. The work would continue in early 2012 to establish a CMDv position to present to the Commission as part of their legislative review.

3.7 Question & Answer (Q&A)

Following queries received from industry and the Member States, discussion took place on the topics below in order to establish the CMDv position. The results of the discussion were presented either as a published Q&A or questionnaire on the CMDv website, a reply directly to the asker of the question or as a document for internal CMDv use.

- Bee products: update on authorised products within the EU (published on CMDv website)
- Member States' completed questionnaire on acceptance of CTD-format for both the quality part of the dossier (Part II) and the active substance master file (published on CMDv website)
- CMDv Q&A on changes to the invented name of the product during MRP/DCP (published on CMDv website)
- User risk assessment & environmental risk assessment requirements at renewal (relating to a question asked by CMDv interested parties specifically to the Czech Republic)
- Withdrawal periods in the different Member States for long-acting amoxicillin products (internal MS questionnaire)
- Extension of shelf-life based on extrapolation (question from industry related to an issue encountered during a specific procedure)
- Question received from industry on applying for a Type II variation for an originator product to add a target species by claiming bioequivalence to another

originator – the company was referred to the published CMDv Q&A no. 63 on 'referring to data in another dossier'
- Questionnaire to Member States on actions taken regarding the risk of possible contamination of veterinary medicinal products following radiation in Japan (information sent to the Commission)
- Member States' questionnaire on all authorised medicinal products in the EU containing mercury (in context of international Treaty on the ban of mercury (information sent to the Commission).
- Member States' questionnaire on handling a change of logo on the product literature (published in Nov-Dec report for release)
- Classification of variation to waive the requirement to perform the target animal batch safety test for immunological veterinary medicinal products (published in Sept-Oct report for release)
- Member States' questionnaire on the authorisation status of roxarsone (4-hydroxy-3-nitrobenzenearsonic acid) – information sent to the Commission.
- Inclusion of non-VMP devices in the packaging of a VMP (published on CMDv website)
- 'EUBAN'[2] questionnaire to identify the network of colleagues dealing with the classification of borderline products (to be published in 2012).

3.8 Transparency and communication

A joint EMA/CMDv working group for the preparation of a veterinary guidance for commercially-confidential information and protection of personal data within the NtA-format dossier was established.

A new fixed agenda point was introduced into the CMDv agenda for sharing of information between Member States on specific product recalls/suspensions, availability issues, supply problems and major variations, e.g. safety issues, withdrawal periods.

The content of the CMDv report for release (RfR) is now worked on by the CMDv members and the secretariat during a designated discussion group. The RfRs are now released only every two months.

4 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.

4.1 Documents revised and finalised in 2011

- The revised CMDv Rules of Procedures were adopted at the September 2011 plenary meeting.
- The Best Practice Guide (BPGs) relating to the new variations Regulation on unforeseen variations (BPG-015) and worksharing (BPG-018) were amended and published in track changes compared to the previous version on the CMDv website.
- Following consultation with the CMDv interested parties, the revised BPG for the repeat use procedure (BPG-003) was finalised and published on the CMDv website.
- The following guidance documents were updated and published on the CMDv website:
  - CMDv contact points for general enquiries (GUI-008)

[2] European Borderline Assessment Network

- List of CMDv members and their qualification (GUI-007)

4.2 New documents:

- CMDv Recommendation for MRP after finalisation of an article 34 referral with a positive decision by the European Commission (EMA/CMDv/422851). Please refer to section 4.3 above for information on this document.

- The draft best practice guidance (BPG-012) on informed consent is a new CMDv document, largely based on the equivalent CMDh recommendations. The document was started in 2010, underwent a consultation with the CMDv's stakeholders but was then put on hold in 2011 due to outstanding points where clarification was requested from the European Commission. The CMDv is considering the Commission's reply and will update the document accordingly in early 2012.

- Template Letter of intent for the submission of a worksharing procedure to the CMDv, published on CMDv website (CMDv-TEM-023e).

- Tables of national e-submission requirements for pre- and post-authorisation applications were finalised and published on the CMDv website.

5 Cooperation

5.1 Heads of Medicines Agencies (HMA)

The CMDv chairperson updated HMA on a regular basis at their meetings and, at the request of HMA, set some specific targets and practical priority actions that the CMDv aimed to fulfil during the coming years. The CMDv chairperson also provided the CMDv with feedback from the HMA meetings.

5.2 Committee for Medicinal Products for Veterinary Use (CVMP)

Agendas and minutes were exchanged and monthly oral reports given to and received from the CVMP. The CMDv Chair and secretary participated in the strategic planning group meetings of the CVMP in order to raise issues of common interest between the CMDv and CVMP, as well as to provide relevant updates on topical CMDv activities.

5.3 Veterinary pharmacovigilance working party (PhVWP-V)

Liaison with the pharmacovigilance working party continued during 2011. The CMDv took note of the agendas and minutes of the PhVWP-V for VMPs. The PhVWP-V chairperson and secretariat presented the latest developments at the CMDv meetings.

5.4 CMDh

Agendas and minutes were exchanged with the CMDh, also monthly verbal reports were given and received. The CMDv took particular interest in the CMDh's discussions on policy issues e.g. regarding generics, data protection periods, validation problems, as well as documents developed by CMDh. A joint virtual meeting took place in September to provide updates on issues of common interest: ongoing revision of the Notice to Applicants, Volume 2A, Chapter 1 (human equivalent to the veterinary Volume 6A; Chapter 1); transparency initiatives within both CMDs; impact of the new human pharmacovigilance legislation on CMDh; proposed updates to the variation classification guideline.

5.5 QRD

Following the CMDv request for the harmonisation of the QRD/MRP/DCP annotated template at the end of 2009 and the work undertaken since then by QRD with the input

of CMDv, the revised template was adopted by CVMP in December and will be published in 2012. The translations update exercise will now be initiated so that the revised templates in each national language can also be published early in 2012.

5.6 Product Index (VMR-I)

A new Product Index on the HMA website generated through CTS (Communication Tracking System) providing information on both human and veterinary medicinal products is under development. The CMDv will continue providing input, as necessary.

5.7 E-Submission and national requirements

Sweden led the CMDv in compiling Member States' national requirements for electronic submissions (and any required paper documentation) for new applications and post-authorisation procedures. The information is presented in tables published under guidance on applications on the CMDv website.

5.8 Representative organisations

Contacts with the established CMDv interested parties, IFAH-Europe, EGGVP and AVC have been maintained and meetings were conducted in February, May and October. It was noted that a significant number of Member States who attended the plenary sessions also attended these meetings. A variety of regulatory issues were addressed, including:

- Implementation of the Variations Regulation, particularly worksharing;
- Discussion of comments provided by the interested parties on the CMDv guidance documents circulated for consultation during 2011.
- Harmonisation of SPCs – industry's perspective on the CMDv's pilot imitative;
- Packaging and labelling requirements;
- The respective contributions of the CMDv and industry stakeholders to the Commission's public consultation on review of the legislative framework for VMPs;
- Miscellaneous regulatory issues encountered in the context of specific MRPs/DCPs e.g. the requirement for environmental risk assessments at the time of renewal; national requirements during validation, fees.

6 The secretariat

The Agency supported the CMDv with a secretariat by preparing and hosting the meetings in London, coordinating and distributing meeting papers, conducting follow-up to meetings, archiving and providing advice, as requested. For each meeting the secretariat prepared minutes including highlighted actions and a report for public release. For the referral procedures the secretariat drew up timetables, notified the applicants, provided them with the list of concerns and organised hearings.

Secretarial support was also given to various working groups.

The secretariat has played a facilitating role in supporting the work of the group to find pragmatic solutions to the intractable issues related to generics and referrals.

In 2011 the secretariat liaised closely with the CVMP, CMDh, PhVWP-V and QRD secretariats and maintained contacts with the national agencies, IFAH-Europe, EGGVP and AVC.

Annex I Referrals to CMDv finalised in 2011

Product Name	Company	Legal base	Target species	Grounds	RMS	CMS	Referring CMS	Outcome
Clavudale 50 mg tablets	Dechra Limited	Art. 13.1	Companion animals	Bioequivalence	UK	AT, BE, CZ, DK, FI, FR, DE, EL, HU, IS, IE, LU, NL, NO, PL, PT, ES, SE	SE, NL	Referred to the CVMP; CVMP opinion in favour of applicant
Clavudale 250 mg tablets	Dechra Limited	Art. 13.1	Companion animals	Bioequivalence	UK	AT, BE, CZ, DK, FI, FR, DE, EL, HU, IS, IE, LU, NL, NO, PL, PT, ES, SE	SE, NL	
Clavudale 500 mg tablets	Dechra Limited	Art. 13.1	Companion animals	Bioequivalence	UK	AT, BE, CZ, DK, FI, FR, DE, EL, HU, IS, IE, LU, NL, NO, PL, PT, ES, SE	SE, NL	
Milaxyn Plus Tablets for Dogs	Chanelle Pharmaceuticals Manufacturing Ltd.	Art. 13.1	Companion animals	Bioequivalence	IE	FR	FR	Positive outcome (but matter of dispute was then referred to the CVMP under article 34 of Dir. 2001/82; ongoing
Strantel Plus Tablets for Dogs	Chanelle Pharmaceuticals Manufacturing Ltd.	Art. 13.1	Companion animals	Bioequivalence	IE	FR	FR	
Prazical Plus Tablets for Dogs	Chanelle Pharmaceuticals Manufacturing Ltd.	Art. 13.1	Companion animals	Bioequivalence	IE	FR	FR	
Voxical Plus Tablets for Dogs	Chanelle Pharmaceuticals Manufacturing Ltd.	Art. 13.1	Companion animals	Bioequivalence	IE	FR	FR	

Product Name	Company	Legal base	Target species	Grounds	RMS	CMS	Referring CMS	Outcome
Prontax 10 mg/ml solution for injection for cattle, sheep and pigs	Pfizer	Art. 13.1	Food producing animals	Environmental	IE	AT, BG, CY, CZ, DK, EE, EL, ES, FI, FR, HU, IS, LT, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK	FR, NL	Referred to the CVMP; ongoing
Prontax 5 mg/ml pour-on solution for cattle	Pfizer	Art. 13.1	Food producing animals	Environmental	IE	AT, BG, DK, ES, FI, FR, HU, IS, NL, NO, PL, PT, RO, SE, SI	FR, NL	Referred to the CVMP; ongoing
PIRETAMOL 300 mg/ml oral solution for pigs	Global Vet Health	Art. 12.3	Food producing animals	Environmental	ES	BE, BG, DE, DK, EL, FR, HU, IT, NL, PL, PT, RO, UK	DE	Positive outcome (applicant presented new ERA data)
Quinoflox 100 mg/ml solution for use in drinking water, chicken and rabbits	Global Vet Health	Art. 13.1	Food producing animals	Antimicrobial resistance	ES	DE, FR, IT, PL, PT, RO, UK	FR	Referral notification not accepted by the CMDv; matter referred CVMP under article 35 of Dir. 2001/82; ongoing
Amoxiclav-VMD 50 mg tablet for cats and dogs	VMD	Art. 13.1	Companion animals	Quality	BE	DE, DK, ES, FR, NL, PL, PT, RO, SE	FR	Positive outcome
Amoxiclav-VMD 250 mg tablet dogs	VMD	Art. 13.1	Companion animals	Quality	BE	DE, DK, ES, FR, NL, PL, PT, RO, SE	FR	
Amoxiclav-VMD 500 mg tablet for dogs	VMD	Art. 13.1	Companion animals	Quality	BE	DE, DK, ES, FR, NL, PL, PT, RO, SE	FR	

Product Name	Company	Legal base	Target species	Grounds	RMS	CMS	Referring CMS	Outcome
Nuflor 300 mg/ml solution for injection for cattle and sheep	Intervet International BV	Annex II (line extension to originator)	Food producing animals	Efficacy	IE	BE, DE, DK, EL, ES, FR, IT, LU, NL, PT, UK	FR	Referred to the CVMP; ongoing
Selenate Long Acting 50 mg/ml Suspension for Injection for Cattle	Cross Vetpharm Group Limited	Art. 13.1	Food producing animals	Safety (withdrawal period)	IE	AT, BE, CZ, DE, DK, EE, ES, FR, HU, LT, LV, PL, RO, SE, SK, UK	DE	Referred to the CVMP but the CVMP rejected notification on legal grounds
Nuflor Swine Once 450 mg/ml solution for injection (pigs)	Intervet International BV	Art. 13.3	Food producing animals	Efficacy	DE	AT, BE, BG, CY, CZ, DK, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK	DK	Referred to the CVMP; ongoing
Cydectin Triclamox pour-on solution for cattle	Pfizer	Art. 13(b)	Food producing animals	Efficacy	FR	AT, BE, DE, DK, EL, ES, FI, IE, IT, LU, NL, PT, SI, UK	BE	Positive outcome (applicant withdrew problem claim)

Annex II List of acronyms

The Agency	European Medicines Agency
ASMF	Active Substance Master File
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
E.C. & EC	European Commission
EEA	European Economic Area (EU+Iceland+Norway+Liechtenstein)
EGGVP	European Group for Generic Veterinary Products
EMA	European Medicines Agency
EUBAN	European Borderline Assessment Network
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agencies
IFAH-Europe	International Federation for Animal Health Europe
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
MS	Member State
NCA	National Competent Authority
NtA	Notice to Applicants
PhVWP	Pharmacovigilance Working Party
Q&A	Question and Answer
QRD	Quality Review of Documents group
RMS	Reference Member State
SMP	Standard Management Procedure
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristics
TIGes-v	Telematics implementation group on e-submissions – vet subgroup
VITERO	Virtual team room = a facility to hold virtual meetings online
VMR-I	Veterinary Mutual Recognition Index