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# ANNUAL REPORT 2009

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## 1 Introduction

This report provides an overview of the work carried out by the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDv) in 2009: the realisation of planned activities following the CMDv Work Plan 2009 (EMA/CMDv/589357/2008) and new items that emerged during the year.

To summarise, the year was characterised by a slight decrease in the number of finalised procedures, particularly those made under the mutual recognition procedure. Reasons for referrals were mainly environmental risk concerns, bioequivalence and efficacy, but most of the concerns were resolved at day 60 with a consequent decrease in the number of referrals to CVMP, (a third compared to 2008). The main focus of the year was for CMDv to finalise all best practice guides in order to be ready for the implementation of the new Variations Regulation. The work which started in 2008 on validation issues was finalised in 2009 and the approach mostly harmonised. Good progress was made on generic applications and the handling of these procedures. Agreement was reached on the harmonisation of the product information templates and the implementation will be carried over to 2010. It was foreseen that National Competent Authorities (NCAs) would be ready to process electronic format applications from 2010. The Rules of Procedure of the CMDv were also updated according to current practice and would be forwarded to Commission for final approval in 2010.

Any follow-up actions are included in the Work Plan 2010 (EMA/CMDv/696111/2009) and/or will be included in future meeting agendas.

An explanatory list of abbreviations used in this report is provided in Annex I.

## 2 Organisational issues

### 2.1 Members

The CMDv is composed of one representative from each Member State of the European Economic Area (EEA) and an observer from the European Commission.

Esther Werner acted as chairperson throughout the year and entered her second year of chairmanship during the second term of her appointment. The vice-chairpersons during the Czech Republic and Swedish presidencies of the Council of the European Union were Iveta Obrovská for the Czech Republic and Alenoosh Abedi for Sweden. The European Commission was represented at the meetings by Jan Henrik Rothert until November when Martinus Nagtzaam took over.

Members from Ireland, Finland and Lithuania were replaced during the year. CMDv appointed a welcome partner among the CMDv representatives to help new members to familiarise themselves with CMDv procedures and to facilitate their immediate participation.

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>).

## 2.2 Meetings

CMDv held monthly meetings at the European Medicines Agency (The Agency) in London, except for the month of August. Meetings were scheduled on Thursday and Friday, directly after the meeting of the Committee for Medicinal Products for Veterinary Use (CVMP). Permanent sub-groups and *ad hoc* working groups met prior to the main plenary session to allow in-depth discussion on document management and the implementation of the new Variations Regulation, harmonisation of the product information templates among the mutual recognition and the centralised procedures, SPC harmonisation and the joint CMDv/IFAH-Europe survey. During the plenary sessions CMDv addressed policy issues, questions from industry (19 in total) and from the Member States, as well as the maintenance of the document management system. Three meetings were held with interested parties' representative organisations, IFAH-Europe, EGGVP and AVC, to discuss topics of mutual interest.

The Czech Republic presidency organised an informal meeting, including a joint session with CVMP in Brno on 25<sup>th</sup> and 26<sup>th</sup> April. The following topics were on the agenda: referrals, optimising procedures and cooperation between committees, status and implementation of the new Variations Regulation, electronic dossier submission, annual survey of procedures and referrals, the communication and tracking system for procedures (CTS Client), treatment of bees, immunological generics & biosimilars and meeting efficiency.

The Swedish presidency also organised an informal meeting including, for the very first time, a joint session with CMD(h). The meeting took place in Uppsala on 5<sup>th</sup> and 6<sup>th</sup> October to broadly discuss subjects of current and common interest. The following topics were on the agenda: rules of procedures, product index, transparency policy, new Variations Regulation with focus on grouped variations and worksharing procedures, SPC harmonisation project, upcoming review of the veterinary pharmaceutical legislation, MUMS and limited markets and electronic dossier submission.

## 2.3 Product discussions

In June 2009, following a 6 month pilot phase, CMDv agreed to use the vitero facility (a client-server based web conferencing software) to replace physical meetings for product discussions which used to take place on the Fridays, in respect of MRP and DCP procedures reaching Day 78 and 198. By doing so Member States' attendance was facilitated by bringing scientific experts, the RMS and the concerned MS to a virtual meeting room, thus reducing the need for travelling time and costs. Vitero also enables issues to be discussed in real time with the relevant experts. Consequently, a longer slot has been freed on Friday mornings in favour of those discussions requiring extra time, oral hearings or referral procedures issues.

Out of 116 products (140 procedures) that reached the end of the mutual recognition (57 MRP) or decentralised (83 DCP) procedure, 42 were discussed. In addition 10 products were discussed in the framework of a referral procedure, for which on 7 occasions, the applicant attended a hearing.

### 3 Authorisation procedures

The core business of CMDv is to facilitate the smooth operation of the MRP and DCP and in particular to consider points of disagreement, raised by Member States in relation to the assessment report, summary of product characteristics (SPC), labelling and package leaflet of a veterinary medicinal product, on the grounds of potential serious risk to human or animal health or to the environment.

Day 90/210 MRP and DCP application procedures decreased by 19% whilst referral procedures increased compared to previous years. However, day 60 referral procedures successfully facilitated the resolution of any outstanding issues. Consequently, the number of procedures sent to CVMP for arbitration more than halved.

#### 3.1 Applications

A total of 140 procedures (variations not included) were finalised, relating to 116 products. Table 1 provides an overview of the number of products that reached the end of the DCP and MRP.

	2009	2008	2007	2006
MRP	50 (57*)	79 (84)	76 (88)	70 (95)
DCP	68 (83*)	70 (89)	26 (30)	4 (3)
Total	<b>116 (140*)</b>	149 (173)	102 (118)	74 (98)

Table 1 MRP and DCP products (procedures\*) finalised

Authorised products decreased by 22% compared with 2008, primarily due to fewer MRP applications.

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

UK	IE	FR	ES	DE	NL	CZ	HU	IT	AT	BE	FI	PT	DK
30	27	25	20	12	9	4	3	2	2	3	1	1	1

Table 2 Reference Member States

#### 3.2 Referrals

Disagreements leading to referrals at CMDv increased compared to 2008; however the number of referrals sent to CVMP for arbitration decreased by a further 27%, compared with last year. In total 21 referral procedures reached day 60 in 2009, of which 17 were resolved, 1 was withdrawn and 3 were referred to CVMP.

	Reaching CMDv procedure, day 60 (and CVMP)			to CMDv as percentage of total products			to CVMP as percentage of total products		
	2009	2008	2007	2009	2008	2007	2009	2008	2007
MRP	9 (1**)	9 (5**)	4 (2)	8%	11%	5%	0,90%	6%	3%
DCP	12 (2**)	9 (4**)	3 (2)	11%	13%	12%	1,90%	6%	8%
Total	21 (3**)	18 (9**)	7 (4)	13%	11%	7%	2,80%	6%	4%

Table 3 Referral procedures to CMDv (to CVMP\*\*).

Although it had been anticipated that the DCP would attract fewer referrals because of the two-phase assessment process, the referral rate is equivalent to that in the MRP. 12 DCP and 9 MRP were referred to CMDv. It should also be noted that this may reflect the role of the RMS during the respective procedures. In MRP the RMS has already authorised the product. However, in the DCP the product is new to both the RMS and CMSs.

The success rate of resolving disagreements during the CMDv referral procedure increased:

2009 87%  
2008 50%  
2007 43%  
2006 25%

## 4 Policy issues

### 4.1 Variations Regulation and revision of Annex I

In anticipation of the publication of a new Variations Regulation in the Official Journal of the European Communities, a joint subgroup with CMD(h) and another one within CMDv (Variations Regulation and document management subgroup), met monthly in order to prepare for implementation. After finalisation of a Best Practice Guide (BPG) for recommendations on unforeseen variations, new and updated BPGs on variations' procedures were developed and published within the timeline to handle the transition period into the implementation of the new Variations Regulation (All new documents are listed under section 5. Documents management).

CMDv representatives participated in the meeting with CMD(h) and the Agency to ensure a harmonised implementation of the Regulation and cooperation on issues of common interest.

### 4.2 Generics

Among the total of applications which reached the end of the procedure in 2009, 81 were generics, of which 22 came under MRP applications and 59 under DCP. For 13 of these generic procedures, day 60 of the referral fell in 2009. 8 procedures ran under the DCP and 5 under the MRP. Overall, generic procedures represented 51% of the total of procedures finalised in 2009.

During the year the group clarified matters related to generics based on precedents which would contribute towards a common interpretation of the main recurrent issues, such as the concept of the European reference product, data protection, SPC

improvements of generics and abridged applications. Outcomes of the discussions were published on the CMDv website.

#### 4.3 Packaging

Following publication of the CMDv conclusions and recommendations document, discussion continues on the ongoing process. CMDv reached agreement with the QRD group to merge the product information templates into one annotated template addressing both the centralised and the MRP & DCP procedures. The implementation work would continue in collaboration with the QRD group in 2010.

#### 4.4 Validation

IFAH-Europe, EGGVP and individual companies reported on various occasions ongoing issues with national validation requirements. Although validation is the responsibility of each individual Member State, invalidation does affect other Member States as it may hold up the start of a procedure.

CMDv finalised its review of the current validation requirements, with the aim to harmonise the approach among the MS, although some discrepancies still exist due to current national legislations.

#### 4.5 Clinical supplies

The use of veterinary medicinal products without marketing authorisations in clinical trials is not covered by European Community legislation. Consequently national rules apply. Concerns were raised over different approaches between the Member States and the problems these may cause.

CMDv carried out a review of the current existing national legislation for veterinary clinical supplies, including the competent authorities, restrictions and additional requirements on import and use of clinical trial supplies, and the requirements for reference products not licensed in the Member State where a trial is conducted.

#### 4.6 SPC harmonisation

SPC harmonisation is important for strengthening consumer confidence, transparency in the market place, cost reduction for industry and to prevent referrals that follow generic applications where the reference product SPC is unharmonised across the EU.

The CMDv decided to re-start the work on the harmonisation of SPCs for VMPs. Contacts with the industry representative organisations were made in order to test a mechanism based on work-sharing and industry participation for harmonising divergent SPCs of the same (nationally) authorised product.

The group prioritised selection criteria and proposed to produce a list of products whose data protection is soon to expire, that may be used as reference product up to 2012 inclusive, with differences in the nationally authorised SPCs that could lead to a referral under article 34 or 35 of Directive 2001/82. Negotiation with a company who welcomed the possibility to act in a SPC harmonisation pilot phase would continue in 2010.

#### 4.7 Environmental risk assessment (ERA) data

With reference to the submission of ERA data, CMDv discussed a common approach to data requirements and concluded that it is not possible to submit ERA data in the form of a 'closed' master file.

#### 4.8 Joint Survey Sub-Group

CMDv agreed with IFAH Europe to continue the survey exercise in order to monitor and control the functioning of the mutual recognition and decentralised procedures. CMDv survey subgroup reviewed in collaboration with IFAH Europe the results raised by industry in response to the 2008 Survey report. Discussion devolved on the targets which would be of benefit to both parties in relation on how to approach the survey exercise in the future.

In 2008, the use of the DCP increased significantly; this had no impact on the MRP, which maintained a constant number of applications. The increased use of the DCP, was mainly considered a consequence of the raise in generic applications.

Article 33(1) referrals to CMDv, under the 60 day procedure, increased in number and were mostly generated by generic applications. Discussion started on the requirements of data package for the products while ensuring innovation.

For 2009 it was agreed to move away from completing individual questionnaires relating to specific products, as a primary source of information for the joint survey report, to a shorter more focussed statistically based report. It was further agreed to supplement this statistical report with a more in-depth perception based analysis on a biannual basis.

#### 4.9 Animal welfare during clinical trials

In connection with the conduct of studies in target species to demonstrate efficacy of VMPs, CMDv discussed how animal welfare during clinical trials comes into play during the assessment of applications of marketing authorisations.

CMDv sought clarification from the European Commission and from the Committee for Medicinal Products for Veterinary Use (CVMP) on the relation between Council Directive 86/609/EEC and the current guidance on the Efficacy of Anthelmintics: Specific Recommendations for Canines (VICH GL19, also known as CVMP/VICH/835/99). The scientific considerations have been debated by CVMP and reported back to CMDv. The Commission legal services are still considering the regulatory aspects and a response is expected during the first half of 2010.

#### 4.10 Honey bees

Following reports on declining honey bee populations in Europe and poor availability of adequate veterinary medicinal products, CMDv prepared an overview of currently authorised products in the Member States to help raise awareness of these products to honey bee professionals and veterinary surgeons. This will help facilitate wider product availability under the prescribing cascade for products not authorised within a Member State.

#### 4.11 Other issues

CMDv discussed a number of other issues, including:

- Informed consent applications;
- Transfer of trade name;
- Change in the name of a product;
- Minor Use Minor Species applications;
- Generics (hybrid applications and bibliographic applications, immunologicals: biosimilars);
- Safety warnings;
- Diluents;
- Clock-off period;

- Starting material of animal origins;
- Global marketing authorisation and protection period;
- Global shortage of acetonitrile.

Discussion also continued on:

- Compliance with EC legislation and protection period;
- Withdrawal of applications and referrals;
- National implementation of the Commission Decision following an Art. 34 and 35 referral procedures.

## **5 Document management**

The document management subgroup was set up in order to promote the quality, consistency and transparency of decision making, to ensure a smooth conduct of procedures, to facilitate the access to documents and to define the areas of responsibilities of the Member States and the secretarial support provided by the Agency respectively.

It was agreed that the Chair of the document management would be taken over every 6 months by the representative of the current Presidency of the Council of Europe.

The document management subgroup meeting was held monthly, jointly with the Variations Regulation subgroup, in order to monitor the development of the main documents necessary to guide in the implementation of the new Variations Regulation.

The development of guidance documents reflected a collaborative work with CMD(h), CVMP, CHMP and the European Commission.

The following documents were finalised:

Revised Best Practice Guides (BPG) on variations Type IA, IB and II;

New BPGs on variation work-sharing and grouping of variations; .

The SOP on disagreement in procedures, Referral Art. 33(1), was also updated to reflect the referral of Type II variations and work-sharing variations to CMDv.

Other documents have been revised on:

- Diluents - Conclusions and recommendations of CMDv;
- Appointment of new members;
- Decentralised Procedure (DCP);
- Procedure on handling of PSURs (MRP/DCP);
- Management of e-mail use during procedures and standardisation of subheadings;
- Contact Points for – General Inquiries - Public Access;
- List of CMDv members and their qualifications;
- Geographical Origin of Biological Starting Materials;
- Vitro Product discussion.

The CMDv secretariat initiated a project on the investigation of the CMDv requirements in order to evaluate the best way forward towards settling a memory database but the project was halted due to other identified priorities.

Based on the initial workplan for 2009, as adopted by CMDv, some documents initially planned to be developed were either put on hold or moved to the workplan for 2010.

A review exercise was performed in the second half of the year to identify all other documents and templates for which revision is required in order to stay consistent with the revised Annex I to Directive 2001/82/EC and the new Variations Regulation.

## **6 Communication and co-operation**

CMDv maintained contact with other groups in the regulatory field to co-ordinate activities of mutual interest.

The CMDv chairperson updated HMA on a regular basis at their meetings and, at request from HMA, addressed the top three priorities for work sharing and other ideas on how to increase efficiency in The European Regulatory Network. The CMDv chairperson also provided CMDv with feedback from the HMA meetings.

Agendas and minutes were exchanged and monthly oral reports given to and received from CVMP. CVMP was consulted on matters relating to clarification on efficacy and immunological issues, and to find a common approach to referrals. Representatives of CMDv joined the CVMP task force on referrals which finalised its mandate in December.

Agendas and minutes were exchanged with CMD(h), also monthly verbal reports were given and received. CMDv took particular interest in discussions on policy issues, e.g. regarding generics, protection periods, validation problems, duplicate applications, rules of procedure and in documents developed by CMD(h). Several documents were used as a basis for the development for veterinary documents as a matter of efficiency and consistency.

CMDv took note of the agendas and minutes of the Pharmacovigilance Working Party for medicinal products for veterinary use (PhVWP-V). The PhVWP-V chairperson and secretariat presented the latest developments at the CMDv meetings.

In the field of information technology, CMDv members and the secretariat were represented in CTS user group and TIGes-v on electronic submission of dossiers.

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

- Implementation of the new Variations Regulation;
- National validation issues;
- Import and labelling requirements for clinical supplies;
- Referrals;
- Animal welfare;
- Availability of products for clinical trials.

A consultation procedure was also open to the interested parties to gain their contribution to a successful implementation of the new Variations Regulation by active participation in the different working groups established to fulfil the new requirements (Procedural guideline, Classification guideline, EU variations Task Force). There was also a CMDv consultation exercise on the new and revised BPGs developed in preparation for the implementation of the revised variations regulation on 1<sup>st</sup> January 2010.

Together with IFAH-Europe and EGGVP the survey report on MRP and DCP in 2008 was finalised. The survey on MRP, DCP and referrals in 2009 was carried out.

## **7 The Secretariat**

The Agency supported 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. 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 sub groups and *ad hoc* 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 packaging, quality and generics.

The secretariat liaised closely with the CVMP, CMD(h) and PhVWP-V secretariats and maintained contacts with the national agencies, IFAH-Europe, EGGVP, AVC and other stakeholders.

## Annex I List of abbreviations

AVC	Association of Veterinary Consultants
CMD(h)	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
DCP	Decentralised Procedure
EEA	European Economic Area (EU+Iceland+Norway+Liechtenstein)
EGGVP	European Group for Generic Veterinary Products
The Agency	European Medicines Agency
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 Authorities
NtA	Notice to Applicants
PhVWP	Pharmacovigilance Working Party
QRD	Quality Review of Documents group
SPC	Summary of Product Characteristics
TIGes-v	Telematics Implementation Group (E-Submissions veterinary)

## Annex II Members, observers and the secretariat

Name	Representing	Function
Esther Werner	CMDv	Chairperson
Eugen Obermayr	Austria	Member
Christophe Debruyne	Belgium	Member Chairperson packaging <i>ad hoc</i> group
Damyan Iliev	Bulgaria	Member
Maria Papaprodromou	Cyprus	Member
Iveta Obrovská	Czech Republic	Member Vice chairperson 01 Jan – 30 Jun
Asbjørn Brandt	Denmark	Member
Helen Mahla	Estonia	Member
Paula Kajaste	Finland	Member (replaced)
Heidi Mustalammi	Finland	Member
Laëtitia Le Letty	France	Member
Gabriele Schweyen	Germany	Member
Ioannis Malemis	Greece	Member
Mária Szabó	Hungary	Member
Jóhann M. Lenharðsson	Iceland	Member
David Murphy	Ireland	Member (replaced)
Paul McNeill	Ireland	Member
Virgilio Donini	Italy	Member
Renate Kuske	Latvia	Member
Brigitte Batliner	Liechtenstein	Member
Laimis Jodkonis	Lithuania	Member (replaced)
Loreta Bobrovičiūtė	Lithuania	Member
Marc Wirtor	Luxembourg	Member (nomination expired)
Kenneth Mifsud	Malta	Member (nomination expired)
Trudy Knol	Netherlands	Member
Tora Gauslaa	Norway	Member
Katarzyne Swiader	Poland	Member (replaced)
Marta Piwonska	Poland	Member
Maria Azevedo Mendes	Portugal	Member
Lollita Taban	Romania	Member
Judita Hederová	Slovakia	Member
Katarina Štraus	Slovenia	Member
Carmen Sanchez	Spain	Member
Alenoosh Abedi	Sweden	Member Vice chairperson 01 Jul – 31 Dec
Gavin Hall	United Kingdom	Member Chairperson survey subgroup and Variations Regulation subgroup
Jan Henrik Rothert	European Commission	Observer (replaced)
Martinus Nagtzaam	European Commission	Observer
Wim Riepma	The Agency/ CMDv secretariat	CMDv secretary (replaced)
Karen Quigley	The Agency/ CMDv secretariat	Interim CMDv secretary (replaced)
Emily Drury	The Agency/ CMDv secretariat	CMDv secretary
Veronica Picciafuoco	The Agency/ CMDv secretariat	Administrative assistant
Bernadett Stoddart	The Agency/ CMDv secretariat	Secretarial assistant
Floriana Veronese	The Agency/ CMDv secretariat	Secretarial assistant

### Annex III Referrals to CMDv finalised in 2009

Product name	Applicant	Legal basis	Target species	Concerns	RMS	CMS	Referred by	Outcome
<b>Pharmasin 2% oral granules</b> NL/V/0129/001	Huvepharma N.V.	Art. 13.2 generic	pig	ecotox	NL	AT, BE, BG, CZ, DE, DK, EL, ES, HU, IE, IT, PL, PT, RO, UK	AT, BE, BG, CZ, DE, EL, HU, IT, NL, PL, PT, RO, UK	Approved
<b>Pharmasin 2% premix</b> NL/V/0130/001	Huvepharma N.V.	Art. 13.2 generic	pig	ecotox	NL	AT, BE, BG, CZ, DE, DK, EL, ES, FR, HU, IE, IT, PL, PT, RO, UK	AT, BE, BG, CZ, DE, EL, FR, HU, IT, NL, PL, PT, RO, UK	Withdrawn
<b>Pharmasin 10% premix</b> NL/V/0130/002	Huvepharma N.V.	Art. 13.2 generic	pig	ecotox	NL	AT, BE, BG, CZ, DK, EL, ES, HU, IE, IT, PL, PT, RO, UK	AT, BE, BG, CZ, EL, HU, IT, NL, PL, PT, RO, UK	Approved
<b>Pharmasin 25% premix</b> NL/V/0130/003	Huvepharma N.V.	Art. 13.2 generic	pig	ecotox	NL	AT, BE, BG, CZ, DK, EL, ES, HU, IE, IT, PL, PT, RO, UK	AT, BE, BG, CZ, EL, HU, IT, NL, PL, PT, RO, UK	Approved
<b>PregSure 3 BVD 1 BVD IBR Marker, emulsion for injection</b>	Pfizer Animal health	Full Art. 12(3)	cattle	ecotox	BE	BG, CY, CZ, DE, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK	BE, BG, CY, DE, EE, EL, ES, FR, HU, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK, UK	Referred to CVMP
<b>Cevazuril 50mg/ml, oral suspension</b>	Ceva Santé Animale	Art. 13.2 generic	pig	ecotox	FR	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SK, UK	CZ, DE, UK	Referred to CVMP
<b>Maprelin XP10 75 ug/ml</b> DE/V/0129/001	Vexy – Pharma GmbH	Full Art. 12(3)	oestrous	efficacy	DE	AT, BE, BG, CZ, EE, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK	BE	Approved

Product name	Applicant	Legal basis	Target species	Concerns	RMS	CMS	Referred by	Outcome
<b>Nelio 5, dog</b> FR/V/0205/001	Sogeval	Art. 13.2 generic	dog	bioequivalence	FR	AT, BE, CZ, DE, DK, EL, ES, FI, IE, IT, LU, NL, PL, PT, RO, SE, UK	NL	Approved
<b>Nelio 20, dog</b> FR/V/0205/002	Sogeval	Art. 13.2 generic	dog	bioequivalence	FR	AT, BE, CZ, DE, DK, EL, ES, FI, IE, IT, LU, NL, PL, PT, RO, SE, UK	NL	Approved
<b>Virbacef Sterile Powder for solution for injection</b> UK/V/0322/001	Virbac S.A.	Art. 13.2 generic	chicken	risk – benefit balance	UK	AT, BE, CZ, EL, FR, HU, IE, PT, SK	FR	Approved
<b>Florkem</b> FR/V/0197/01	CEVA Sante' Animale	Art. 13.2 generic	chicken	ecotox	FR	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK	AT, BE, BG, CY, CZ, DE, EE, EL, ES, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SK, UK	Approved
<b>Pracetam powder</b>	Sogeval	Full Art. 12(3)	pigs	ecotox	FR	AT, BE, BG, CZ, DE, DK, ES, HU, IT, LI, NL, PL, PT, RO, SK, UK	AT, BE, BG, CZ, ES, FR, HU, IT, NL, LI, PL, PT, RO, SK, UK	Approved
<b>Procapen</b>	aniMedica GmbH	Art. 13.2 generic	cattle, calves, horses, pigs	Environmental (withdrawal period)	DE	DK, DE, ES, FI, HU, NL, PL, RO, SE	DE, DK, ES, FI, HU, PL, RO, SE	Approved
<b>Poulvac Bursa Plus</b> UK/V/0335/001	Fort Dodge Animal health Ltd.	Full Art. 12(3)	chicken	risk-benefit balance	UK	BE, BG, CZ, DE, DK, EE, EL, ES, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK	BE	Referred to CVMP
<b>Api Life Var</b> IT/V/0123/001	Chemical Laif	Art. 13.2 generic	bees	Quality, PhV, Tolerance, Combination	IT	DE, EL, ES, FR, UK	ES	Approved

Product name	Applicant	Legal basis	Target species	Concerns	RMS	CMS	Referred by	Outcome
<b>Chloromed CT Line 15% Oral Powder</b>	Univet Limited	Full Art. 12(3)	pig	Environmental (Lack of Tier A studies)	IE	BE, CZ, DE, NL, PL, RO, UK	DE	Approved
<b>Chloromed CT Line Premix for medicated feed</b>	Univet Limited	Full Art. 12(3)	pig	Environmental (Lack of Tier A studies)	IE	BE, CZ, DE, NL, PL, RO, UK, DE, DK, UK	DE	Approved
<b>Cyductin TriclaMox Oral Solution for Sheep</b>	Fort Dodge Animal health Ltd.	13.b fixed combination	sheep	Environmental	FR	AT, BE, DE, DK, EL, ES, IE, IS, IT, LU, NL, PT, SE, UK	BE, DE	Approved
<b>Prazitel Plus tablets for Dogs and Puppies</b>	Chanelle Pharmaceuticals Manufacturing Ltd.	Art. 13.2 generic	dogs, puppies	Efficacy	IE	AT, BE, BG, CZ, DE, DK, EL, ES, FI, HU, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK, UK	UK	Approved
<b>Exitel Plus tablets for Dogs and Puppies</b>	Chanelle Pharmaceuticals Manufacturing Ltd.	Art. 13.2 generic	dogs, puppies	Efficacy	IE	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, HU, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SK, UK	UK	Approved
<b>Cazitel Plus tablets for Dogs and Puppies</b>	Chanelle Pharmaceuticals Manufacturing Ltd.	Art. 13.2 generic	dogs, puppies	Efficacy	IE	BE, BG, CZ, DE, EE, EL, ES, FI, HU, IT, LT, LV, NL, PL, PT, RO, SI, SK, UK	UK	Approved
<b>Tempestop 30% oral solution for pigs</b>	Vetpharma Animal Health S.L.	13.a established use	pig	Efficacy	HU	CZ, PL, PT, RO, SK	PL	<i>Ongoing, Day 60 in 2010</i>
<b>Amoxivet</b>	Sogeval	Art. 13.2 generic		Quality	FR	BE, DE, ES, HU, IT, NL, PL, PT, UK	ES	<i>Ongoing, Day 60 in 2010</i>
<b>Chanectin 0.8mg/ml oral solution for sheep</b>	Chanelle Pharmaceuticals Manufacturing	Art. 13.2 generic	Sheep	Bioequivalence, environmental	IE	FR, UK	FR	<i>Ongoing, Day 60 in 2010</i>

Product name	Applicant	Legal basis	Target species	Concerns	RMS	CMS	Referred by	Outcome
Animec 0.8mg/ml oral solution for sheep	Chanelle Pharmaceuticals Manufacturing	Art. 13.2 generic	sheep	Bioequivalence, environmental	IE	BE, FR, EL, ES, PL, PT, UK	FR	<i>Ongoing, Day 60 in 2010</i>