



EMEA/CMDv/33261/2009 – final
London, 12 March 2009

ANNUAL REPORT 2008

7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

CONTENTS

1	Introduction.....	3
2	Organisational issues	3
2.1	Members	3
2.2	Meetings.....	3
2.3	Performance evaluation	4
3	Authorisation procedures.....	5
3.1	Applications.....	5
3.2	Referrals.....	6
4	Policy issues.....	6
4.1	Generics.....	6
4.2	Packaging	7
4.3	Validation	7
4.4	Variations Regulation and revision of Annex I.....	7
4.5	Environmental risk assessment.....	8
4.6	Ectoparasitocidal products	8
4.7	Joint Survey Sub-Group	8
4.8	Other issues	8
5	Document management	9
6	Communication and co-operation.....	10
7	The secretariat	11
	Annex I List of abbreviations.....	12
	Annex II Members, observers and the secretariat	13
	Annex III Referrals to CMDv finalised in 2008	14

1 Introduction

This report provides an overview of the work carried out by the Coordination Group for Mutual Recognition and Decentralised Procedures (CMDv) in 2008: the realisation of planned activities following the CMDv Work Plan 2008 (EMEA/CMDv/434974/2006) and new items that emerged along the way.

In brief the year can be characterised by an ever growing number of procedures, particularly those made under the decentralised procedure; an increasing number of referrals relating to environmental risk concerns; good progress was made in processing generic applications; simplifying packaging requirements and reducing the number of validation issues. The CMDv also started preparing for the implementation of the new Variations Regulation. Esther Werner was re-elected chairperson to serve a further 3 year term. The group evaluated its functioning following its creation (formally VMRFG) under the amended legislation.

Any follow-up actions are included in the Work Plan 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 per Member State, including Iceland, Liechtenstein and Norway, and an observer from the European Commission.

Esther Werner acted as chairperson throughout the year and she was re-elected for a second 3 year term on 12 November. The vice-chairpersons during the Slovenian and French presidencies of the Council of the European Union were Katarina Štraus for Slovenia and Sandrine Guët and Laëtitia Le Letty for France. The European Commission was represented at the meetings by Jan Rotherth.

Members from Bulgaria, the Czech Republic, Lithuania, Poland, Romania and Sweden 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.

2.2 Meetings

CMDv held monthly meetings at the European Medicines Agency (EMA) 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, harmonisation of packaging requirements, implementation of the variations regulation and the joint CMDv/IFAH-Europe survey. During the plenary sessions CMDv addressed policy issues, questions from industry (27 in total) and from the Member States, as well as the maintenance of the document management system. Out of 149 products (176 procedures) that reached the end of the mutual recognition (MRP) or decentralised (DCP) procedure, 76 were discussed at a meeting. In addition 12

products were discussed in the framework of a referral procedure, for which on 9 occasions the applicant attended a hearing. Three meetings were held with industry representative organisations IFAH-Europe, EGGVP and AVC to discuss topics of mutual interest. One further meeting with IFAH-Europe took place within the framework of the *ad hoc* working group on packaging requirements.

The Slovenian presidency organised an informal meeting, including a joint session with CVMP in Bled on 26 and 27 May. The following topics were on the agenda: the new Variations Regulation, the Communication and Tracking System (CTS), the joint CMDv/IFAH-Europe survey, validation issues reported by industry, exchange of views on the need for a memory database, an update on the revision of the MRL (maximum residue limit) Regulation, experience with referral procedures, cooperation between CMDv and CVMP to promote the availability of veterinary medicines, pharmacovigilance and also packaging issues.

The French presidency also organised an informal meeting including a joint session with CVMP. The meeting took place in Paris on 1 and 2 October. On the agenda were: the outcome of the CMDv self assessment exercise and opportunities for improvement, a further exploration of development of a memory database, opportunities for improving veterinary pharmaceutical legislation, the implementation of the new Variations Regulation, a review of validation issues, the role of CMDv in relation to pharmacovigilance, issues with generics and bioequivalence studies.

2.3 Performance evaluation

The majority of serving CMDv members completed their first three year term of appointment in October. On this occasion they evaluated the functioning of the group in view of its agreed mandate and any new responsibilities taken on since November 2005, to recognise its strengths and to identify opportunities for improvement.

Information has been gathered by means of a questionnaire filled in by the members, one per Member State. The questions were related to members, meetings, the documentation system, communication and cooperation as well as future developments. The final section provided an opportunity to make any comments on the effectiveness of CMDv and possible improvements.

The results indicated that the members are generally satisfied with the functioning of the group including its decisions, the conduct of meetings, the supporting documentation that has been developed and also the support provided by EMEA. CMDv is highly valued as a platform for sharing knowledge and experience.

Opportunities for improvement relate to resources made available by the Member States, the distribution of work, the contribution of experts, the decision making process and external communication.

CMDv has decided to further improve its effectiveness by amongst others:

- providing introductory training to new members;
- actively involving members in discussions and distributing work more equally;
- revising the meeting format to allow faster decision making;
- starting a pilot with virtual product discussions (Vitero) to enhance expert participation, to reduce travelling costs and to explore the possibility of flexible

procedure start dates; the latter could reduce peak work loads in the national agencies.

Areas for improvement identified outside the direct remit of CMDv include:

- the available resources in the National Agencies for CMDv related work;
- the mandate of members;
- availability and compatibility of ICT facilities in the national agencies;
- communication at national level.

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.

A strong growth was noted in new applications and consequently referrals to CMDv and CVMP increased. However, the Member States were more successful in resolving disagreements in the CMDv referral procedure as compared to previous years. This was in part due to greater clarification received from the Commission in relation to generics and also following precedents set by the CVMP.

3.1 Applications

A total of 176 procedures (variations not included) were finalised, relating to 151 products. Table 1 provides an overview of the number of products that reached the end of the DCP and MRP.

	2008	2007	2006
MRP	79	76	70
DCP	70	26	4
Total	149	102	74

Table 1 MRP and DCP (products) finalised

Products reaching the end of the procedure increased by 48% compared with 2007, and doubled that of 2006. As expected, the strongest growth was seen in the DCP, but the MRP maintained its position as most used procedure.

In spite of the strong increase in work load, the Member States managed to process the applications within the legal deadlines. However, comments were received from industry that the limited capacity in some Member States has led to long waiting times (submission slots) before a procedure can start. Member States taking on the role of RMS are shown below in table 2.

UK	IE	DE	FR	NL	ES	BE	SK	CZ	HU	NO	DK	SE	IT	PT	AT
53	20	18	17	9	9	6	4	3	3	2	1	1	1	1	1

Table 2 Reference Member States

3.2 Referrals

Disagreements leading to referrals to CMDv and CVMP more than doubled compared to 2007, as shown in table 3. This can be attributed to concerns related to the environmental risk assessment of generic products as well as efficacy and quality issues. However, no generics were referred to CVMP because of efficacy or safety concerns related to the reference products. This was a major issue in 2007, but Commission guidance and CVMP precedents were applied. For more information, see also section 4.1.

	number of referrals to CMDv (and CVMP)			to CMDv as percentage of total products			to CVMP as percentage of total products		
	2008	2007	2006	2008	2007	2006	2008	2007	2006
MRP	9 (5)	4 (2)	7(6)	11%	5%	10%	6%	3%	9%
DCP	9 (4)	3 (2)	1 (0)	13%	12%	25%	6%	8%	0%
Total	18 (9)	7 (4)	8(6)	11%	7%	11%	6%	4%	8%

Table 3 Referrals

Although it had been anticipated that the DCP would attract less referrals because of the two phase assessment, the referral rate is equivalent to that in the MRP.

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

2008 50%
2007 43%
2006 25%

4 Policy issues

4.1 Generics

HMA endorsed in January the general principles for the handling of generic applications, as agreed by CMDv in December 2007¹. Based on these principles a guidance document for the processing of generic applications through MRP and DCP was developed and published in July. Key aspects of the guidance are: early recognition of differences between national authorisations of the reference product, exchange of information on the reference product between the Member States, and restricting referrals under article 33(4)² of generics to CVMP to potential serious risk issues regarding quality, bioequivalence, injection site residues or the environment. As a result no generics were referred to CVMP under article 33(4) for concerns relating to the reference product - this was the main reason for referring generic products in 2007. Alternatively reference products and, where applicable, generic products have been referred under article 34 or article 35, under which provisions the areas of potential serious risk concerns can be addressed.

A sharp increase was seen in generics being referred under article 33(4) because of potential serious risk concerns in relation to the environmental risk assessment.

¹ CMDv Annual Report 2007 EMEA/CMDv/17781/2008

² of Directive 2001/82/EC as amended

Since the implementation of Directive 2004/28/EC Member States gave different interpretations to the environmental risk assessment requirements for generic products. Clarifications from the European Commission were received whilst procedures were ongoing. Most Member States recognised the difficult position some applicants had been put into as the understanding of the requirements had changed during the procedure. They therefore accepted post authorisation commitments for completing the environmental risk assessment, considering that immediate risks to the environment were unlikely given the data already provided.

4.2 Packaging

Package information (labelling) is an important matter for the user but also a factor for the commercial viability of placing products on smaller markets. Industry noted several regulatory problems and IFAH-Europe addressed these at a workshop in Prague in the spring of 2006. This led CMDv to conduct surveys in 2006 and 2007 to explore the nature and extent of the problems. An *ad hoc* working group on packaging and labelling was set up to develop solutions for the packaging problems.

Following the preparatory work of the *ad hoc* group, Member States accepted several industry proposals for change, such as using 3x English mock ups (as minimum) for multilingual labels and publishing templates in all language versions. CMDv also issued recommendations for industry, HMA, the European Commission and EMEA, regarding changes outside the remit of the group. The conclusions and recommendations were all summarised in a document that was published on the CMDv website in November. A follow up meeting with industry representative organisations IFAH-Europe, EGGVP and AVC was scheduled to take place in January 2009.

4.3 Validation

IFAH-Europe, EGGVP and individual companies reported on various occasions 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.

In June IFAH-Europe sent a list of problems as reported by their member companies. This list was discussed at the informal CMDv meeting in Paris in October and further investigated in subsequent weeks. At its regular meeting in December CMDv concluded that some of the listed national validation requirements had already been repealed, had not been enforced or would be amended in the near future. It was noted that some validation problems could be avoided if applicants read the Notice to Applicants carefully before submitting an application. A template letter confirming the type of application, which can be optionally sent by the applicant to the authorities, was developed as a way to further minimise problems with validation.

IFAH-Europe was informed of the outcome of the investigation and the discussion would continue in 2009.

4.4 Variations Regulation and revision of Annex I

In anticipation of the publication of a new Variations Regulation³ in the Official Journal of the European Communities, a joint subgroup with CMDh was formed to prepare for implementation. At first a Best Practice Guide for recommendations on unforeseen variations was developed, as this aspect of the Regulation would apply

³ Commission Regulation (EC) No 1234/2008

shortly after publication. Input was also given to the classification of variations document.

CMDv representatives participated in the meeting with CMDh and EMEA to ensure a harmonised implementation of the Regulation and cooperation on issues of common interest.

4.5 Environmental risk assessment

At the request of EMEA, a group of CMDv members continued to provide CVMP with regulatory advice on the reflection paper on the implementation of environmental risk assessment.

The European Commission clarified that for applications for generic products a data package equivalent to that for a full application has to be submitted. How this has been dealt with is described in section 4.1.

Regarding the assessment of data packages, questions arose on the use of data available in the public domain, such as peer reviewed articles, summary reports, the USA Food and Drug Agency and opinions of CVMP. In response to questions from CMDv, the European Commission indicated that public data can be used, but that it should contain sufficient detail to perform an assessment in its own right. Otherwise the public data could be used as supportive evidence only, and requirement to conduct studies would apply.

Nevertheless, it became apparent that Member States' views differ with regard to the level of detail required to be allowed to draw conclusions on published data. By the end of the year further clarification was awaited from the European Commission.

4.6 Ectoparasiticide products

Following queries from industry, CMDv investigated whether teat dips and flea collars are classified as veterinary medicinal product or biocides and which authorities deal with them. It appeared that the classification differs from Member State to Member State. It was recognised that this is not an ideal situation, but the classification often depends on national legislation. To make the work of potential applicants easier, an overview of the situation in the Member States was published.

4.7 Joint Survey Sub-Group

During the year CMDv reviewed the concerns raised by industry in response to the 2007 Survey report. These were around issues of participation in product discussions, majority voting, the number of minor questions raised and shortening the CMDv referral phase. It was noted that participation in product discussions had improved over that in 2007, with experts being involved directly in discussions via video conference or telephone conference. CMDv also agreed that its 60-day referral process was relatively successful and therefore agreed to maintain the full 60 days before any onward referral to CVMP is made. It was difficult to judge whether the situation regarding the number of minor questions asked had changed. Questions are raised in relation to specific products and the supporting data packages and therefore it is not possible to define absolute guidance. Finally, Members did discuss the move to majority voting but this is something that is outside the remit of CMDv. Further detail can be found in the 2008 Joint Survey Report.

4.8 Other issues

CMDv discussed a number of other issues, including:

- Variations on vaccination schemes;

- Use of article 13.1 versus article 13.3 of Directive 2001/82/EC;
- Mesylate-containing products;
- Species extension of MRP products;
- Companies' right to appeal;
- Products intended for rabbits;
- Informed consent applications;
- Transfer of trade name;
- Change in the name of a product;
- Sunset clause;
- Copper sulphate containing products;
- Minor Use Minor Species applications;
- Hybrid applications;
- Safety warnings.

Discussion also continued on:

- The regulatory status of blood products;
- Compliance with EC legislation and protection period;
- Work sharing;
- Withdrawal of applications and referrals.

5 Document management

Following extensive discussions throughout the year, CMDv developed three fundamental documents:

- guidance on generics;
- guidance on actions after a CVMP referral opinion Art. 33;
- conclusion and recommendation document on packaging.

All existing documents were reviewed for any need for revision, with particular focus on maintaining consistency. The following documents were harmonised:

Standard operating procedures (SOP)

- Disagreement in procedures – Referral to CMDv and oral explanation;

Best practice guides (BPG)

- MRP;
- DCP;
- Reference Member State;

Guidance documents (GUI)

- Exchange of documentation relating to a RVMP between RMS (which also updated the title, as previously called "Documentation when a RMP is not authorised in the MS").

Also, following further discussion at the packaging *ad hoc* group it was agreed to align the previously published CMDv templates on product information with the EMEA QRD templates for the centralised procedures, thus requiring all MS to update each respective language. This work started in 2008 with the publication of updated translations, as available.

Following discussion which started in 2007 the secretariat assumed the role of web-editor for the new HMA/CMDv website, thus assuming the authority to update and replace new documents as necessary. Based on experience, CMDv agreed upon a revised structural proposal of the website. Confirmation is awaited from Germany who holds the overall responsibility of the website design and structure.

Following the new "Variations Regulation" the work for the development of guidance documents and templates started according to priorities set by the European Commission. The first provisional document to have been finalised is the Best Practice Guide on Article 5, unforeseen variations.

A discussion on the organisation of the regulatory and scientific memory system continued and the CMDv secretariat initiated a project on the investigation of the CMDv requirements in order to evaluate the best way forward.

Based on the initial work plan for 2008 as adopted by CMDv, some documents initially planned to be developed were either put on hold or moved to the work plan for 2009.

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 addressed to HMA questions regarding diluents, generics, environmental risk assessment and referrals. 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. The CMDv chairperson also participated in the CVMP Strategic Planning Group meetings.

Furthermore, 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, 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. The CMDv occasionally attended PhVWP-V 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. IFAH-Europe provided a presentation on the use of a data matrix as information carrier on packs.

Contacts with industry representative organisations 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 Variations Regulation;
- Packaging;
- National validation issues;
- Import and labelling requirements for clinical supplies;
- Referrals.

Together with IFAH-Europe and EGGVP the survey report on MRP and DCP in 2007 was finalised. The survey on MRP, DCP and referrals in 2008 was carried out.

7 The secretariat



EMA supported CMDv with a secretariat by preparing and hosting the meetings in London, conducting follow-up to meetings, archiving and providing advice. All meetings were paperless. 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
EMA	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
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
Paskal Zhelyazkov	Bulgaria	member (replaced)
Damyán Iliev	Bulgaria	member
Maria Papaprodromou	Cyprus	member
Daniel Dušek	Czech Republic	member (replaced)
Iveta Obrovská	Czech Republic	member
Asbjørn Brandt	Denmark	member
Helen Mahla	Estonia	member
Paula Kajaste	Finland	member chairperson document management subgroup
Sandrine Guët	France	member (replaced) vice chairperson 01 Jul – 31 Aug
Laëtitia Le Letty	France	member vice chairperson 01 Sep – 31 Dec
Gabriele Schweyen	Germany	member
Ioannis Malemis	Greece	member
Mária Szabó	Hungary	member
Jóhann M. Lenharðsson	Iceland	member
David Murphy	Ireland	member
Virgilio Donini	Italy	member
Renate Kuske	Latvia	member
Brigitte Batliner	Liechtenstein	member
Kristina Sudikienė	Lithuania	member (replaced)
Laimis Jodkonis	Lithuania	member
Marc Wirtor	Luxembourg	member (nomination expired)
Kenneth Mifsud	Malta	member (nomination expired)
Trudy Knol	Netherlands	member
Tora Gauslaa	Norway	member
Katarzyna Swiader	Poland	member (replaced)
Joanna Kubisa	Poland	member
Maria Azevedo Mendes	Portugal	member
Elena Luminita Paraschiv	Romania	member (replaced)
Lollita Taban	Romania	member
Judita Hederová	Slovakia	member
Katarina Štraus	Slovenia	member vice chairperson 01 Jan – 30 Jun
Carmen Sanchez	Spain	member
Christina Wik	Sweden	member (replaced)
Alenoosh Abedi	Sweden	member
Gavin Hall	United Kingdom	member chairperson survey subgroup and variations regulation subgroup
Karin Krauss	European Commission	observer (replaced)
Jan Henrik Rothert	European Commission	observer
Wim Riepma	EMEA CMDv secretariat	CMDv secretary
Veronica Picciafuoco	EMEA CMDv secretariat	administrative assistant
Bernadett Stoddart	EMEA CMDv secretariat	secretarial assistant

Annex III Referrals to CMDv finalised in 2008

Product name	Applicant	Type	Target species	Concerns	RMS	CMS	Referred by	Outcome
Ketopropig 100mg/ml Oral Solution for Pigs	Fort Dodge Animal Health	Art. 13	Pig	Efficacy	UK	AT, BE, CZ, DE, DK, ES, FR, HU, IT, NL, PL, PT	FR	Approved
HatchPak Avinew, Aqueous Suspension	Merial	Art. 12	Chicken	Quality	HU	AT, BE, CZ, DE, EL, ES, FI, FR, IE, IT, LT, LU, LV, NL, PL, PT, SK, UK	DE	Approved
AMOXIVAL 200 T	SOGEVAL	Art. 13	Dog	Efficacy	FR	AT, BE, DE, DK, EL, ES, FI, HU, IT, NL, PL, PT, SE, UK	IE	Approved
AMOXIVAL 400 T	SOGEVAL	Art. 13	Dog	Efficacy	FR	AT, BE, DE, DK, EL, ES, FI, HU, IT, NL, PL, PT, SE, UK	IE	Approved
Pharmasin 100 Water Soluble Granules, oral solution	Huvepharma N.V.	Art. 13	Chicken, pig, turkey, calf	Environmental (DE) Safety (IT)	NL	AT, BE, BG, CZ, DE, DK, ES, HU, IE, IT, PL, PT, RO, UK	DE, IT	Referred to CVMP by DE
Unisol (Aviflox)	Universal Farma S.L	Art. 13	Chicken, turkey	Environmental	IE	BE, CZ, DE, PL	DE	Referred to CVMP
Enro-K	Laboratories Karizoo SA	Art. 13	Chicken, turkey	Environmental	IE	BE, CZ, DE, PL	DE	Referred to CVMP
Tilmovet 25%, oral solution for pigs, poultry and calves	Huvepharma NV	Art. 13	Pig, poultry, calf	Environmental	BE	AT, BG, CZ, DE, DK, EL, ES, FR, HU, IE, IT, NL, PL, PT, RO, UK	DE	Approved
Enrogal 50 mg/ml solution for injection	Pharmagal s.r.o	Art. 13	Pig, calf, dog	Safety and efficacy	SK	PL	PL	Approved

Product name	Applicant	Type	Target species	Concerns	RMS	CMS	Referred by	Outcome
Clavobay Lactating Cow Intramammary Suspension	Bayer Healthcare	Art. 12	Cattle	Quality and efficacy	UK	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IS IT, LT, LU, LV, MT, NL, NO, PL, PT, SE, SI, SK, RO	BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IS IT, LT, LU, LV, MT, NL, NO, PL, PT, SE, SI, SK	Referred to CVMP
Shotaflor 300 mg/ml Solution for injection for cattle	Virbac SA	Art. 13	Cattle	Environmental	UK	AT, BE, DE, DK, EL, ES, FR, IE, IT, NL, PT	DE, NL, FR	Referred to CVMP
Fenflor 300 mg/ml solution for injection for CATTLE	Gosmore Ltd.	Art. 13	Cattle	Environmental	UK	AT, BE, DE, ES, FR, IE, IT, NL, PL, PT	DE, NL, FR	Referred to CVMP
Pyceze	Novartis Animal Vaccines Limited	Art. 12	Pig	Environmental	UK	DE, DK, EL, ES, FR, IE, IS, IT, NO, PL	DE	Approved
APPM Respipharm, Suspension for injection	Pharmagal Bio spol. S.r.o.	Art. 12	Pig	Quality and efficacy	SK	ES, PL	ES	Referred to CVMP
Alpha Max	Pharmaq AS	Art. 12	Salmon, trout	Safety	NO	IE, UK	IE, UK	Approved
Tildren	Ceva Santé Animale	Art.12	Horse	Safety and efficacy	UK	AT, BE, CY, CZ, DK, FI, FR, DE, EL, HU, IE, IT, LU, NL, NO, PL, PT, SK, ES, SE	BE, SE	Referred to CVMP
Uniferon 20% Vet.	Pharmacosmos A/S	Art. 13	Piglet	Quality	DK	DE, EE, EL, FI, HU, NL, PL, PT	DE	Referred to CVMP
Pharmasin 25% premix for medicated feed	Huvepharma N.V.	Art. 13	Pig	Environmental	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	Ongoing Day 60 in 2009

Product name	Applicant	Type	Target species	Concerns	RMS	CMS	Referred by	Outcome
Pharmasin 2% oral granules	Huvepharma N.V.	Art. 13	Pig	Environmental	NL	AT, BE, BG, CZ, DE, DK, EL, ES, HU, IE, IT, PL, PT, RO, UK	AT, BE, BG, CZ, DE, EL, HU, IT, PL, PT, NL, RO, UK	Ongoing Day 60 in 2009
Pharmasin 2% premix for medicated feed	Huvepharma N.V.	Art. 13	Pig	Environmental	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	Ongoing Day 60 in 2009
Pharmasin 10% premix for medicated feed	Huvepharma N.V.	Art. 13	Pig	Environmental	NL	AT, BE, BG, CZ, DK, EL, ES, HU, IE, IT, PL, PT, RO, UK	AT, BE, BG, CZ, EL, HU, IT, PL, PT, NL, UK	Ongoing Day 60 in 2009