



EMA/CMDv/17781/2008
London, 14 March 2008

ANNUAL REPORT 2007

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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 (CMD(v)) in 2007: the realisation of planned activities following the CMD(v) Work Plan 2007 (EMEA/CMDv/434974/2006) and new items that emerged along the way.

Any follow-up actions are included in the Work Plan 2008 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 CMD(v) is composed of one representative per Member State, including Norway, Iceland and Liechtenstein, and an observer from the European Commission.

Esther Werner was the appointed chairperson for the whole year. The vice-chairpersons during the German and Portuguese presidencies of the Council of the European Union were, respectively, Gabriele Schweyen and Maria Mendes. The European Commission was represented at the meetings by Karin Krauss.

The group welcomed members from the newly acceded member states, Bulgaria and Romania.

Members from Hungary, Iceland, Liechtenstein, Poland, Portugal and Sweden were replaced during the year. A full list of members and observers is provided in Annex II. The list of CMD(v) members, including their professional qualification, is published on the CMD(v) website (<http://www.hma.eu/157.html>).

2.2 Meetings

CMD(v) 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, labelling of products containing diluents, harmonisation of packaging requirements and the joint CMD(v) / IFAH-Europe survey. During the plenary sessions CMD(v) addressed policy issues, questions from industry (15 in total) and from the Member States as well as the maintenance of the document management system. Out of 102 products that reached day 78 or day 198 of the MRP and DCP respectively, 69 were discussed at a meeting. In addition 8 products were discussed in the framework of a referral procedure, for which on 4 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 diluents.

The German presidency organised an informal meeting, including a joint session with CVMP in Berlin on 3 and 4 May. Topics discussed included the revision of

Commission Regulation (EC) No 1084/2003 (Variation Regulation), the functioning of the DCP, the use of the European Reference Product; the application of the sunset clause, GMP and related validation issues; together with CVMP environmental risk assessment, the status of referral procedures, the recommendations from the HMA task force on availability and the HMA strategy implementation group.

3 Authorisation procedures

The core business of CMD(v) 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.

During the year a strong growth was noted in new applications, whilst the number of disagreements leading to referrals declined.

3.1 Applications

The number of products for which a procedure started and the number of products for which a procedure ended are presented in table 1. Where there were multiple procedures for the same product in different strengths, this has been counted as one product. It should also be noted that the presented numbers of started and finalised procedures in a calendar year are not directly linked. Started procedures may not have finalised at the end of 2007, whilst finalised procedures may have started before 1 January 2007.

| | started | | finalised | | referred to CMD(v) | | resolved | | referred to CVMP | | pending 31/12 | |
|-------|---------|-----|-----------|-----|-----------------------|-----|----------|-----|---------------------|-----|------------------|-----|
| | '07 | '06 | '07 | '06 | '07 | '06 | '07 | '06 | '07 | '06 | '07 | '06 |
| MRP | 75 | 77 | 76 | 70 | 4 | 7 | 3 | 4 | 2 | 6 | 0 | 1 |
| DCP | 65 | 25 | 26 | 4 | 3 | 1 | 1 | 0 | 2 | 0 | 1 | 1 |
| Total | 140 | 102 | 102 | 74 | 7 | 8 | 4 | 4 | 4 | 6 | 1 | 2 |

Table 1. Products MRP, DCP and referrals

New applications went up by 37% compared to 2006, marking industry's confidence in the European market and also in the way in which the DCP and MRP are managed by the Member States. Growth was observed in applications for generic veterinary medicinal products and the use of the DCP soared whilst the number of MRP reduced slightly.

The DCP was introduced in October 2005. Compared to a national application followed by MRP, it provides a considerably shorter time-span for companies to gain access to multiple markets. Furthermore, it provides industry the flexibility and cost-efficiency to target the markets of their interest in comparison with the centralised procedure.

3.2 Referrals

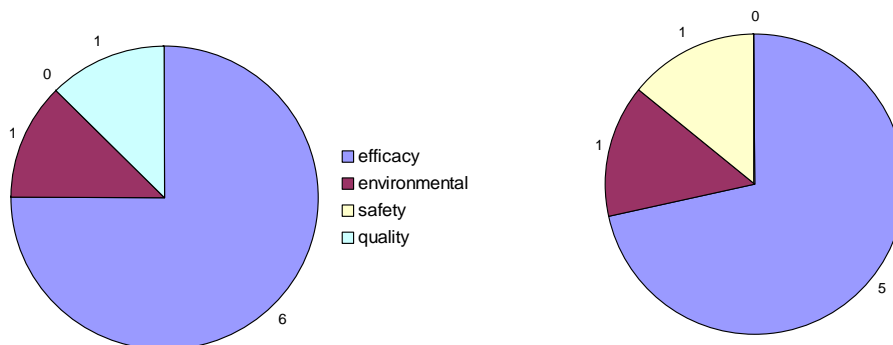
Procedures were also more successful than a year earlier, as the number of products referred to CMD(v) at the end of a MRP or DCP went down from 11% in 2006 to 7% in 2007. Contributing factors to the improved success rate have been:

- experience gained with previous referrals;
- increased dialogue between authorities and with applicants;
- a better understanding of potential serious risk following the Guideline on the definition of a potential serious risk to human or animal health or for the environment in the context of Article 33(1) and (2) of Directive 2001/82/EC as amended — March 2006 (2006/C 132/08).

The timetable was adjusted in a flexible manner to cater for the specific requirements of each procedure, although the 60 day time limit was strictly adhered to.

CMD(v) did not seek nor require scientific advice from CVMP with a view to preventing or resolving referrals.

The main area of disagreement remained efficacy (graph 1 and 2). Notably all 5 efficacy related cases were generic applications. The acceptance of efficacy and safety of generic products, where the reference product is not, or is differently authorised in a CMS, was subject to intensive discussions (see paragraph 4.1)



Graph 1 Area of disagreement 2006

Graph 2 Area of disagreement 2007

Products for which the referral procedure ended in 2007 are listed in Annex III. For 4 products the disagreement was resolved whilst 4 products were referred to CVMP for arbitration.

4 Policy issues

In relation to the implementation of the amendment of Directive 2001/82/EC by Directive 2004/28/EC and following questions from industry and competent authorities, discussions were held:

- to devise or amend policies regarding generic products;
- on environmental risk assessment;
- on diluents;
- on public access to documents and information;
- on harmonisation of packaging requirements;
- on the implementation of the sunset clause;
- and also several other issues.

4.1 Generic products

The discussion on the handling of generic applications in cases where the reference product is not authorised in a Member State (European Reference Product), or where the SPC for the reference product differs between Member States, was carried over from 2006. This was further fuelled by 5 referral procedures for generic products. Following advice from the European Commission and CVMP's opinion on the first referral case, CMD(v) agreed to compile a set of principles for the handling of generic applications.

By December the following set of general principles, which are intended to set out how Member States will interact with each other and deal with generic applications being considered through a European procedure, was agreed and forwarded to HMA for their endorsement.

- The Member States will accept the SPC of the reference product which is usually that of the RMS. The SPC of the reference product may include additional indications, species and routes of administration as well as a different withdrawal period compared to the originator product in the CMS. Nevertheless, these differences should be accepted unless there are justified grounds for refusal based on a potential serious risk.
- The Member States should accept the European reference product (ERP) based on mutual trust by recognising the assessment performed by the Member State which has authorised the ERP according to the data requirements and standards in force at the time of the application.
- When a CMS has within its territory a product authorised by the same applicant as the local reference product, that CMS may take into account the knowledge it has gained from its original assessment and subsequent PSUR information. This information may be utilised when making the decision to authorise the generic product.
- The extent of data / information exchange should be proportionate and restricted only to the principle of minimum data exchange. The assessment report prepared by the RMS in respect of the original reference product, whenever possible and if available, or the confidential annex prepared by the RMS, should be sufficient to allow the CMS to agree to an authorisation without requesting further data or documentation. The need for further documentation should be the exception rather than the rule and should be fully justified.
- The RMS will ensure that it provides an assessment of the relevant data on the reference product where there are significant differences between SPCs in other CMS e.g. species and indications, based on information submitted by the applicant.

- Where a potential serious risk is identified in relation to efficacy or safety (except safety to the environment), a CMS can request additional clarification / documentation from the RMS on the reference product, particularly if that CMS has previously refused an indication, species or similar product.
- The vertical harmonisation between the SPCs of the reference and generic products should be encouraged. However, in the event of safety concerns or potential serious risk to human/ animal health or for the environment the harmonisation should be enforced.
- Each application for a generic product must contain an Environmental Risk Assessment (ERA).

CMD(v) took note of advice from the European Commission that safety and efficacy concerns for generic products, not related to differences with the reference product or the environmental risk assessment, cannot be addressed in the framework of a referral under Article 33 of Directive 2001/82/EC as amended (a referral following MRP or DCP). In such instance the CMS or RMS should consider triggering a referral under Article 34 (divergent opinion) or Article 35 (community interest) of the Directive involving the reference product.

The group also recognised that CVMP set an important precedent in its arbitration on the case of Equibactin vet Oral Paste for Horses, referred by CMD(v) because a CMS considered the dosage scheme to be inadequate, possibly also leading to antimicrobial resistance development. CVMP indicated, however, that Equibactin is a generic and therefore the only concerns that could be addressed were in case of any differences between reference and generic product that would justify different conclusions on the safety or efficacy. In its opinion the Committee concluded that:

- Equibactin vet proved to be essentially similar to the reference product;
- the same conclusions on efficacy and safety apply equally to both products;
- the objections raised should not prevent the granting of a marketing authorisation.

4.2 Environmental risk assessment

In the context of ongoing MRP/DCP and as a principle matter, the need for and extent of an environmental risk assessment for generic products was discussed. The European Commission confirmed in June that an environmental risk assessment has to be carried out for originator and generic products alike. However, in the view of the Commission, the need to provide an environmental risk assessment for a substance which has been used for some time does not automatically mean that the data to be provided needs to be the same as for a new substance.

Ecomectin Oral Paste for Horses, a generic product, was referred to CVMP because of concerns over the environmental risk assessment. The Committee, having considered the matter, concluded that, since the product is intended for use in a minor species (horses) that is reared and treated similarly to a major species, the conclusions on the environmental risk assessment of the major species apply, the product should be exempt from providing a Phase II assessment and that no risk mitigation measures should be included in the SPC of the product.

At the request of EMEA, a group of CMD(v) members contributed to the finalisation of the CVMP reflection paper on the implementation of environmental risk assessment.

4.3 Diluents

The ad hoc working group on diluents was established to resolve and prevent problems with the administrative handling of products containing diluents. Their conclusions and recommendations were subsequently adopted by CMD(v) and published on CMD(v) website.

The issues addressed can be divided to issues related to:

- Validation of a procedure: one or more procedures to follow and dossier requirements;
- End of a procedure: SPC and labelling of the diluents.

A way of handling procedures with one or more diluents or optional diluents has been developed. Where needed one main procedure including several sub-procedures, depending on the number of diluents, will be created. If required the applicant has to commit to informally submit separate SPCs and product literature. However, the core European SPC, package leaflet and labelling to be agreed remain those of the RMS. An overview of those Member States in which the Applicant is required to maintain separate authorisations was also provided and published.

Being part of the authorisation the diluent is mentioned in the SPC as part of the product or as an optional diluent.

If the dossier contains sufficient information and adequate reference is made in the SPC to the diluent, and further the package leaflet does refer clearly to the diluent, a general label would be preferred for the diluent. The particulars to appear on the immediate packaging (label) were laid down in a general template.

The use of a trade name only for the diluent was generally not supported, but would be possible together with a brief description (properties diluent for example). A more descriptive way of naming, without numbers and names of specific marketing authorisations was accepted.

4.4 Access to documents

CMD(v) adheres to openness with regard to the conduct of its tasks. Therefore, a policy has been developed for the publication of documents and the handling of requests for access to documents.

The reference member state archives documents related to procedures and the secretariat archives documents related to the organisation of CMD(v). Documents are classified either as "Public" or "Confidential". Certain public documents are published by default, such as: the rules of procedures, the names and qualifications of the CMD(v) members, annual work plans and reports, reports for release of meetings, reports of the MRP/DCP survey, agreed SPCs, public assessment reports, best practice guides, guidance documents, position papers as well as question and answer documents on topics of general interest. Other public documents will be made available upon request.

Requests for access to confidential documents archived by the secretariat are handled by EMEA pursuant to its Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents. Requests for access to confidential documents archived by a Member State, are dealt with by that Member State according to their national provisions. The conduct of the DCP was made more

transparent as CMD(v) decided to make the assessment report available on a standard basis to the applicant at day 70 of the procedure.

4.5 Packaging

Package information (labelling) is an important 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 CMD(v) to conduct a survey in 2006 to explore the nature and extent of the problems.

When the ad hoc working group on diluents had finalised its work, an ad hoc working group on packaging and labelling was set up by CMD(v) to develop solutions for the packaging problems. The first concrete step was to publish the CMD(v) templates for product information in all official EEA languages, including Icelandic and Norwegian on the CMD(v) website. The group also circulated a questionnaire to identify the legal background of each problem and any potential scope for change in each Member State concerned. By the end of the year an overview was created and it appeared that the questionnaire itself had resulted in each of the Member States reviewing and on occasion changing their position. However, many outstanding obstacles appeared to be related to national or European legislation beyond the control of the National Competent Authorities. The outcome and discussions with industry on how to move forward were scheduled for the beginning of 2008.

4.6 Sunset clause

Pursuant to Article 28 of the amended Directive 2001/82/EC, authorisations for products that have not been marketed within three years of issuing the marketing authorisation, or products which have not been marketed for a period of three consecutive years, shall become invalid, unless there are fully justified reasons to maintain the marketing authorisation. The implementation of the sunset clause for products authorised nationally or via MRP or DCP is the responsibility of each Member State.

CMD(v) developed a guidance document, addressing questions that a marketing authorisation holder may have on how the competent authority of a Member State will monitor the marketing of any veterinary medicinal product, which has been authorised via MRP or DCP. The Guidance document comes with an annex on the implementation date of Directive 2001/82/EC (as amended) in each Member State.

4.7 Other issues

CMD(v) discussed a number of other issues, including:

- The regulatory status of blood products, teat dips and flea collars.
- Work sharing in the assessment of national variations.
- The CVMP reflection paper on assessment of quality of generic products.
- The possibility to change the RMS during or after MRP/DCP.
- The use of multiple reference products.
- Compliance with post authorisation commitments.
- How to handle products in case of expiry of an antigen storage period.
- Referring to the data of another product without the consent of the marketing authorisation holder after expiry of the data protection period, in the context of an application under article 13b.
- Different withdrawal periods depending on route of administration or depending on the weight of the animal.

5 Document management

CMD(v), supported by the subgroup for document management, continued its work in developing and maintaining the document management system. Following extensive discussions, the following selection of documents were newly developed, revised and agreed by CMD(v) based on a priority list.

Standard operating/management procedures (SOP/SMP)

- Advice from CMD(v) on regulatory matters
- Archiving
- Access to documents
- VMR-Index database

Best practice guides

- Automatic validation of MRP
- Processing of SPC, labelling and packaging provided in support of MRP and DCP
- Reference Member State

Guidance documents

- Clock start dates
- Sunset Clause
- Position paper on the change of the RMS
- Conclusion and recommendation paper on diluents

CMD(v) templates on product information were developed for publication in all official EU languages including Icelandic and Norwegian.

Further documents were elaborated and reviewed by the group to enable it to comply with the functions established in the Directive and the Rules of procedure as well as to ensure the effective functioning of the CMD(v).

Following the launch of the new HMA website, the CMD(v) website was also reviewed and discussed. It was agreed by CMD(v), HMA and EMEA that the secretariat would assume the role of web-editor. However, this had not come into effect by the end of the year as authorisation and training from the webmaster were awaited.

A discussion on the organisation of the regulatory and scientific memory system was initiated.

6 Co-operation with other groups

CMD(v) maintained contact with other groups in the regulatory field to co-ordinate activities of mutual interest.

The CMD(v) chairperson updated HMA on a regular basis at their meetings and addressed to HMA questions regarding diluents, generics, environmental risk assessment and referrals. She also provided CMD(v) with feedback from the HMA meetings.

Agendas and minutes were exchanged and monthly oral reports given to and received from CVMP. The CMD(v) chairperson also participated in the CVMP Strategic Planning Group meetings.

Furthermore, agendas and minutes were exchanged with CMD(h), also monthly oral reports were given and received. CMD(v) 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.

CMD(v) 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 CMD(v) meetings. The CMD(v) occasionally attended PhVWP-V meetings. The pilot project on PSUR work sharing was initiated and prepared together. The CMD(v) and PhVWP-V have agreed to develop a document on interaction between PhVWP-V and CMD(v), to ensure timely and effective exchange of information between both groups regarding the outcome of product related scientific and regulatory issues. In the field of information technology, CMD(v) members 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.

7 Stakeholders

Contacts with industry representative organisations IFAH-Europe, EGGVP and AVC have been maintained and meetings were conducted in March, June and October. At those meetings a variety of regulatory issues were addressed, including:

- CMD(v) best practice guides under consultation;
- The IFAH-Europe – CMD(v) survey;
- IFAH-Europe packaging proposals;
- EGGVP questions regarding the eligibility of various generic application constructions;
- Diluents;
- Referrals.

Together with IFAH-Europe the survey report on the MRP in 2006 was finalised. The survey on MRP, DCP and referrals in 2007 was carried out.

CMD(v) also approached the Federation of Veterinarians of Europe (FVE) and the European consumer group BEUC, offering the opportunity to discussion areas of their interest.

8 The secretariat



EMA supported CMD(v) 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, 4 in total.

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 diluents, packaging 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) |
| CMD(v) | 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 |
| MRP | Mutual Recognition Procedure |
| MAH | Marketing Authorisation Holder |
| MS | Member State |
| NtA | Notice to Applicants |
| PhvWP | Pharmacovigilance Working Party |
| QRD | Quality Revision Documents |
| 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 | CMD(v) | chairperson |
| Eugen Obermayr | Austria | member |
| Christophe Debruyne | Belgium | member chairperson packaging ad hoc group |
| Paskal Zhelyazkov | Bulgaria | member |
| Maria Papaprodromou | Cyprus | member |
| Daniel Dušek | Czech Republic | member |
| Asbjørn Brandt | Denmark | member |
| Helen Mahla | Estonia | member |
| Paula Kajaste | Finland | member chairperson document management subgroup |
| Laëtitia Le Letty | France | member |
| Gabriele Schweyen | Germany | member vice chairperson (01 Jan - 30 Jun) |
| Ioannis Malemis | Greece | member |
| Gábor Kulcsár | Hungary | member (replaced) |
| Mária Szabó | Hungary | member |
| Ingibjorg Pálsdottir | Iceland | member (replaced) |
| Jóhann M. Lenharðsson | Iceland | member |
| David Murphy | Ireland | member |
| Virgilio Donini | Italy | member |
| Renate Kuske | Latvia | member |
| Peter Malin | Liechtenstein | member (replaced) |
| Brigitte Batliner | Liechtenstein | member |
| Kristina Sudikienė | Lithuania | member |
| Marc Wirtor | Luxembourg | member |
| Kenneth Mifsud | Malta | member |
| Trudy Knol | Netherlands | member chairperson diluents ad hoc group |
| Tora Gauslaa | Norway | member |
| Agata Dyrkacz | Poland | member (replaced) |
| Katarzina Swiader | Poland | member |
| Margarida Alves | Portugal | member (replaced) |
| Maria Azevedo mendes | Portugal | member vice-chairperson (01 Jul -31 Dec) |
| Elena Luminita Paraschiv | Romania | member |
| Judita Hederová | Slovakia | member |
| Katarina Štraus | Slovenia | member |
| Carmen Sanchez | Spain | member |
| Vera Franzén | Sweden | member (replaced) |
| Christina Wik | Sweden | member |
| Gavin Hall | United Kingdom | member chairperson survey subgroup |
| Karin Krauss | European Commission | observer |
| Wim Riepma | EMEA CMD(v) secretariat | CMD(v) secretary |
| Veronica Picciafuoco | EMEA CMD(v) secretariat | administrative assistant |
| Bernadett Mózes-Stoddart | EMEA CMD(v) secretariat | secretarial assistant |

Annex III Referrals to CMD(v) finalised in 2007

| Product name | Applicant | Type | Target species | Concerns | RMS | CMS | Referred by | Outcome |
|-------------------|---------------------------|---------|----------------|-------------|-----|--|----------------|------------------|
| Compagel | Boehringer Ingelheim | Art. 13 | Horses | Efficacy | DE | DE, FR, NL, SE, UK | FR, SE | Referred to CVMP |
| Ecomectin | Eco Animal Health Ltd | Art. 13 | Horses | Environment | IE | BE, CY, DE, DK, EL, ES, FI, FR, HU, IT, NL, NO, PT, SE, UK | DE, FR, IT, UK | Referred to CVMP |
| Equibactin vet | Le Vet BV | Art. 13 | Horses | Efficacy | NL | AT, BE, DE, DK, EL, ES, FI, FR, HU, IE, IT, LU, NO, PL, PT, SE, UK | FR | Referred to CVMP |
| Gallimune Se + St | Merial Animal Health Ltd | Art. 12 | Chickens | Efficacy | UK | AT, BE, CY, CZ, DE, DK, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, SI, SK | NL | Approved |
| Kenostart SD | CID Lines NV | Art. 13 | Cattle | Efficacy | UK | PL, PT, SE, | SE | Approved |
| Nobivac KC | Intervet International BV | Art. 12 | Dogs/Cats | Safety | UK | DK, IT, NO, PL, SE | DK, NO | Approved |
| Paracillinvet | Intervet International BV | Art. 13 | Cattle/Pigs | Efficacy | IT | FR, DE | FR, DE | Approved |
| Solacyl | Eurovet | Art. 13 | Pigs | Efficacy | NL | AT, BE, CZ, DE, DK, ES, FR, HU, IE, IT, LT, PL, UK | IE | Referred to CVMP |