10 June 2014
EMA/286257/2014
Veterinary Medicines Division

# Monthly report on application procedures, guidelines and related documents for veterinary medicines

May 2014

This report, which is updated every month, provides current information related to the volume and evaluation of pre- and post-authorisation applications for medicinal products for veterinary use received by the European Medicines Agency (EMA) for the current and previous three years on:

- scientific-advice requests;
- applications for initial evaluations, variations, extensions and renewals concerning marketing authorisations (MAs);
- applications for initial evaluations, extensions, modifications and extrapolations for maximum residue limits (MRLs);
- arbitration and referral procedures;
- requests for classification of products as Minor Use/Minor Species (MUMS)/limited market.

In addition, the report includes a summary table of the opinions issued by the Committee for Medicinal Products for Veterinary Use (CVMP) in the current year, as well as a list of adopted guidelines and other public guidance documents.

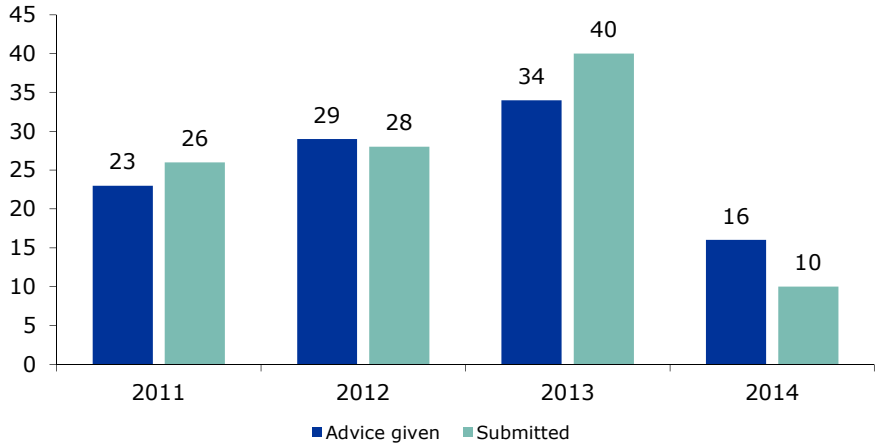
The purpose is only to provide ongoing factual information. Commentaries and analysis are provided in the Agency's annual reports.

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

## Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

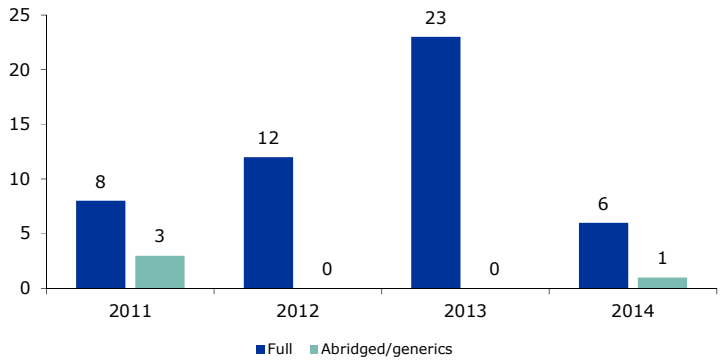
| Scientific-advice requests | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Submitted | 26 | 28 | 40 | **10** |
| Advice given | 23 | 29 | 34 | **16** |

**Scientific advice requests sumbmitted and andvice given**

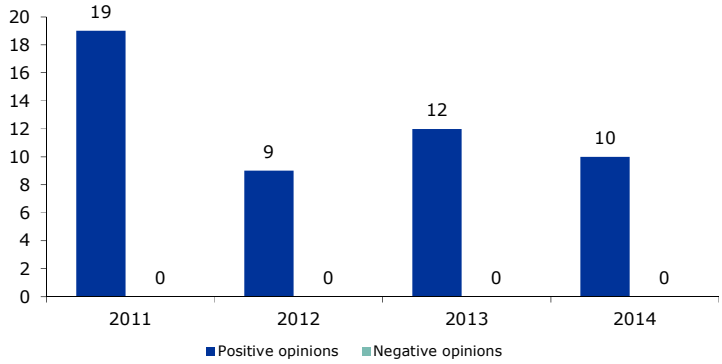



| Initial evaluation of marketing-authorisation applications | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Full (submitted) | 8 | 12 | 23 | **6** |
| Abridged/generics (submitted) | 3 | 0 | 0 | **1** |
| Withdrawals | 0 | 1 | 0 | **0** |
| Positive opinions | 19 | 9 | 12 | **10** |
| Negative opinions | 0 | 0 | 0 | **0** |

**Pre-authorisation: submissions of MA applications by type**




**Pre-authorisation: outcome of the evaluation of MA applications**

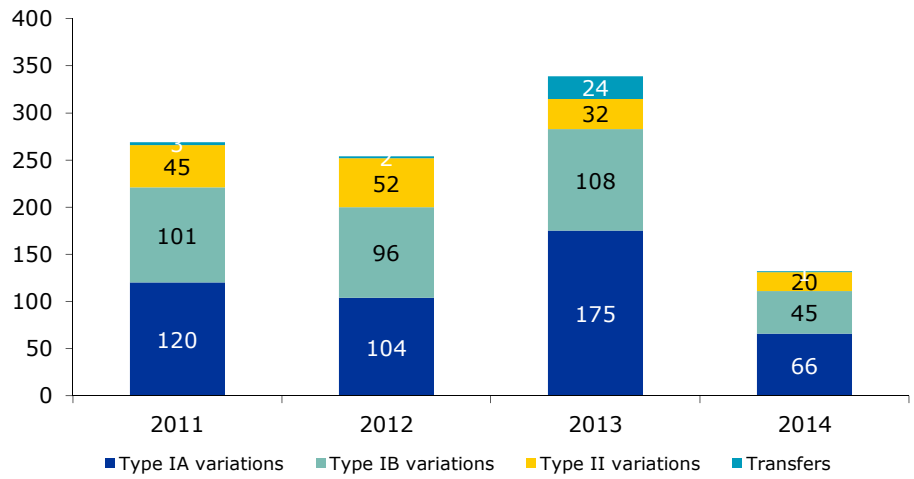


| Marketing authorisations | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Granted | 24 | 8 | 13 | **7** |
| Withdrawals | 1 | 3 | 3 | **1** |
| Not renewed | 0 | 0 | 0 | **0** |

| Extensions — applications | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Submitted | 7 | 8 | 5 | **1** |
| Withdrawals | 0 | 1 | 0 | **1** |
| Positive opinions | 4 | 10 | 9 | **2** |
| Negative opinions | 0 | 0 | 0 | **0** |

| Variations — applications submitted | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Type-IA variations | 120 | 104 | 175 | **66** |
| Type-IB variations | 101 | 96 | 108 | **45** |
| Type-II variations | 45 | 52 | 32 | **20** |
| Transfers | 3 | 2 | 24 | **1** |

**Post-authorisation: variations and transfers submitted**




| Renewals — applications | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Submitted | 14 | 10 | 16 | **7** |
| Positive opinions | 12 | 10 | 14 | **8** |
| Negative opinions | 0 | 0 | 0 | **0** |

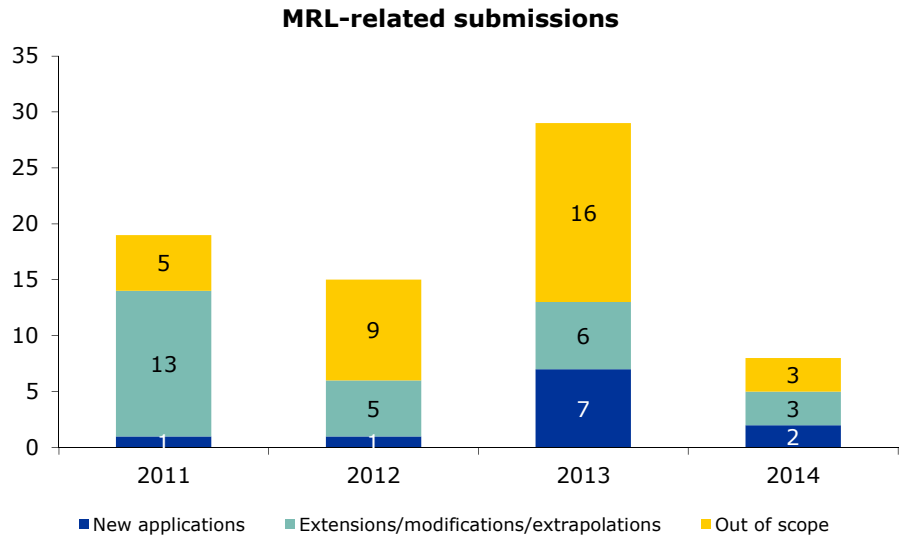
| Establishment of MRLs for new substances — applications | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Submitted | 1 | 1 | 7 | **2** |
| Withdrawals | 0 | 1 | 1 | **0** |
| Positive opinions [1] | 4 | 1 | 4 | **2** |
| Negative opinions | 0 | 0 | 0 | **0** |

[1] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances with previously provisional MRLs.

| Extensions/modifications/extrapolations of MRLs[2] — applications | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Submitted | 13 | 5 | 6 | **3** |
| Withdrawals | 2 | 0 | 0 | **0** |
| Positive opinions [3] | 12 | 8 (2) | 8 | **0** |
| Negative opinions | 0 | 0 | 0 | **0** |

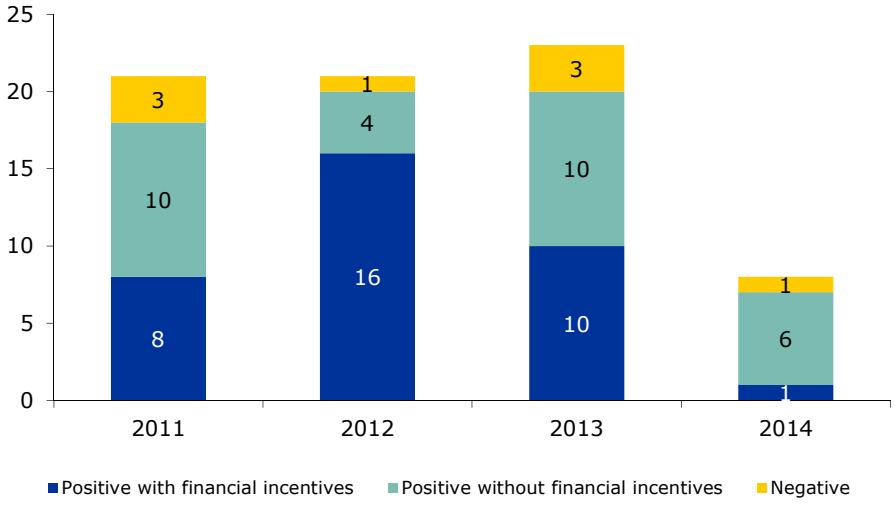
[2] Including requests from the European Commission under Article 11 of Regulation (EC) No. 470/2009.
[3] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances with previously provisional MRLs. Re-examination of opinions are indicated in brackets.

| Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests | | | | |
|---|---|---|---|---|
| | 2011 | 2012 | 2013 | 2014 |
| Submitted | 5 | 9 | 16 | **3** |
| Agreed | 10 | 6 | 9 | **4** |
| Not agreed | 0 | 1 | 2 | **0** |
| Scientific advice recommended | 0 | 0 | 6 | **0** |



| MUMS/limited-market classification — requests | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|
| Positive with financial incentives | 8 | 16 | 10 | **1** |
| Positive without financial incentives | 10 | 4 | 10 | **6** |
| Negative | 3 | 1 | 3 | **1** |

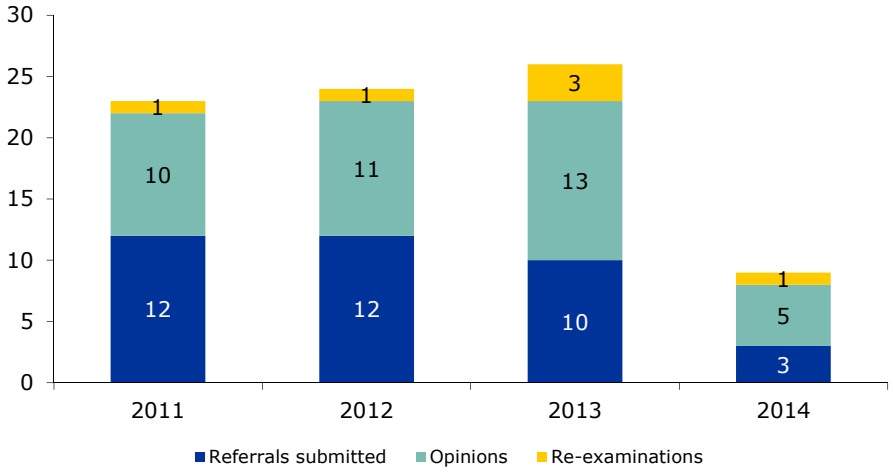
**MUMS/limited market classification requests**




| Arbitrations and referrals | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|
| Arbitrations and referrals submitted | 12 | 12 | 10 | **3** |
| Opinions[3] | 10 (1) | 11 (1) | 13 (3) | **5 (1)** |

[3] Re-examination of opinions in brackets.

**Arbitrations and referrals submitted and opinions**



## CVMP opinions in 2014 on medicinal products for veterinary use

***Positive opinions***

| **Product**<br>• Invented name<br>• INN/Common name | **Marketing authorisation holder** | **Therapeutic area**<br>• Target species<br>• Summary of indication | **EMA/CVMP**<br>• Validation<br>• Opinion<br>• Active time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Transmission to EC<br>• Decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • **Fungitraxx**<br>• Itraconazole | • Avimedical B.V | • Ornamental birds<br>• Treatment of aspergillosis and candidiasis. | • 07/11/2012<br>• 16/01/2014<br>• 210<br>• 225 | • 16/01/2014<br>• 12/02/2014<br>• 12/03/2014<br>• 17/03/2014<br>• C 123 of 25/04/2014 |
| • **Equisolon**<br>• Prednisolone | • LE VET B.V. | • Horse<br>• Alleviation of clinical recurrent airway obstruction (RAO) in combination with environmental control. | • 10/10/2012<br>• 16/01/2014<br>• 210<br>• 253 | • 16/01/2014<br>• 12/02/2014<br>• 12/03/2014<br>• 14/03/2014<br>• C 123 of 25/04/2014 |
| • **Parvoduk**<br>• Muscovy duck parvovirus | • MERIAL | • Muscovy duck<br>• Vaccine against duck parvovirosis and Derzsy's disease. | • 07/11/2012<br>• 13/02/2014<br>• 203<br>• 260 | • 13/02/2014<br>• 10/03/2014<br>• 11/04/2014<br>• 15/04/2014<br>• C 165 of 29/05/2014 |
| • **Versican Plus DHPPi/L4R**<br>• Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus, leptospiras and rabies virus | • Zoetis Belgium SA | • Dog<br>• Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough), parvovirus disease, leptospirosis and rabies. | • 20/03/2013<br>• 13/03/2014<br>• 203<br>• 155 | • 13/03/2014<br>• 09/04/2014<br>• 07/05/2014 |

| Product<br>• Invented name<br>• INN/Common name | Marketing authorisation holder | Therapeutic area<br>• Target species<br>• Summary of indication | EMA/CVMP<br>• Validation<br>• Opinion<br>• Active time<br>• Clock stop | European Commission<br>• Opinion received<br>• Transmission to EC<br>• Decision<br>• Notification<br>• Official Journal |
|---|---|---|---|---|
| • **Versican Plus DHPPi/L4**<br>• Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus and leptospiras | • Zoetis Belgium SA | • Dog<br>• Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough), parvovirus disease and leptospirosis. | • 15/05/2013<br>• 13/03/2014<br>• 210<br>• 92 | • 13/03/2014<br>• 09/04/2014<br>• 07/05/2014 |
| • **Vectra Felis**<br>• Dinotefuran, pyriproxyfen | • Ceva Santé Animale | • Cats<br>• Treatment and prevention of flea infestations. | • 13/12/2012<br>• 10/04/2014<br>• 210<br>• 274 | • 10/04/2014<br>• 06/05/2014 |
| • **Versican Plus Pi**<br>• Canine parainfluenza virus | • Zoetis Belgium SA | • Dog<br>• Vaccine against canine parainfluenza virus. | • 12/06/2013<br>• 08/05/2014<br>• 210<br>• 120 | • 08/05/2014 |
| • **Versican Plus DHPPi**<br>• Canine distemper virus, canine adenovirus, canine parvovirus and canine parainfluenza virus | • Zoetis Belgium SA | • Dog<br>• Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough) and parvovirus disease. | • 12/06/2013<br>• 08/05/2014<br>• 210<br>• 120 | • 08/05/2014 |
| • **Eryseng Parvo**<br>• Porcine parvovirus, erysipelothrix | • Laboratorios HIPRA, S.A. | • Pig<br>• Vaccine against parvovirus disease and swine erysipelas. | • 13/02/2013<br>• 08/05/2014<br>• 210<br>• 239 | • 08/05/2014 |
| • **Eryseng**<br>• Erysipelothrix | • Laboratorios HIPRA, S.A. | • Pig<br>• Vaccine against swine erysipelas. | • 13/02/2013<br>• 08/05/2014<br>• 210<br>• 239 | • 08/05/2014 |

## CVMP opinions in 2014 on establishment of MRLs

***Positive opinions***

| Product<br>• Substance | **Target species** | **EMA/CVMP**<br>• Validation<br>• Opinion<br>• Active time<br>• Clock stop | **European Commission**<br>• Opinion received<br>• Decision<br>• Notification<br>• Official Journal |
|---|---|---|---|
| • Barium selenate | • All food producing species | • N/a<br>• 10/04/2014<br>• 130<br>• N/a | • 11/04/2014 |
| • Clodronic acid (in the form of disodium salt) | • *Equidae* | • 11/12/2013<br>• 08/05/2014<br>• 148<br>• 0 | • 14/05/2014 |

## Arbitrations and referrals in 2014

***Ongoing procedures***

| **Type of procedure** | Date<br>• Clock start<br>• CVMP opinion | Product<br>• Product name<br>• INN |
|---|---|---|
| • Referral under Article 35 of Directive 2001/82/EC | • 12/09/2012 | • Suanovil 20 and associated names, Captalin and associated names and generic products thereof, including pending applications<br>• Spiramycin |
| • Referral under Article 34 of Directive 2001/82/EC | • 10/10/2012<br>• 10/04/2014 | • Linco-Spectin 100 and its associated names<br>• Lincomycin, spectinomycin |
| • Referral under Article 34 of Directive 2001/82/EC | • 07/11/2012<br>• 09/04/2014 | • Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names<br>• Enrofloxacin |
| • Referral under Article 30(3) of Regulation 726/2004 | • 10/01/2013 | • Lidocaine<br>• Lidocaine |
| • Referral under Article 35 of Directive 2001/82/EC | • 10/04/2013 | • All veterinary medicinal products containing altrenogest to be administered orally to pigs and horses<br>• Altrenogest |

| **Type of procedure** | Date<br>• Clock start<br>• CVMP opinion | Product<br>• Product name<br>• INN |
|---|---|---|
| • Referral under Article 35 of Directive 2001/82/EC | • 16/05/2013<br>• 09/04/2014 | • Baytril 2.5% injectable, Baytril 5% injectable, Baytril 10% injectable and associated names and related veterinary medicinal products authorised under Article 13 of Directive 2001/82/EC<br>• Enrofloxacin |
| • Referral under Article 35 of Directive 2001/82/EC | • 06/11/2013<br>• 08/05/2014 | • All veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs<br>• Tylosin |
| • Referral under Article 33(4) of Directive 2001/82/EC | • 16/05/2013<br>• 15/01/2014 | • Norbonex 5-mg/ml pour-on solution for beef and dairy cattle<br>• Eprinomectin |
| • Referral under Article 33(4) Directive 2001/82/EC | • 16/05/2013<br>• 11/12/2013<br>• 09/04/2014 (re-examination) | • Fiprex CAT 52.5 mg spot-on solution for cats, Fiprex S 75 mg spot-on solution for dogs, Fiprex M 150 mg spot-on solution for dogs, Fiprex L 300 mg spot-on solution for dogs and Fiprex XL 412.5 mg spot-on solution for dogs<br>• Fipronil |
| • Referral under Article 13 of Regulation (EC) No. 1234/2008 | • 12/02/2014 | • Resflor solution injectable<br>• Florfenicol, flunixin |
| • Referral under Article 13 of Regulation (EC) No. 1234/2008 | • 12/02/2014 | • Ubrolexin intramammary suspension for lactating dairy cows<br>• Cephalexin, kanamycin |
| • Referral under Article 35 of Directive 2001/82/EC | • 12/03/2014 | • All veterinary medicinal products containing gentamicin presented as solutions for injection to be administered in horses<br>• Gentamicin |

## Guidelines and working documents in 2014

***CVMP quality***

| Reference number | Document title | Status |
|---|---|---|
| EMA/CHMP/CVMP/QWP/70278/2012-Rev.1 | Guideline on process validation for finished products. Information and data to be provided in regulatory submissions. | Adopted January 2014<br><br>(End of consultation 31 October 2012) |
| EMA/CHMP/CVMP/QWP/441071/2011 | Guideline on stability testing for applications for variations to a marketing authorisation. | Adopted January 2014<br><br>(End of consultation 31 January 2012) |
| [Published on EMA website] | Revised Q&A on limits for microbiological quality for premixes for medicated feeding stuffs which contain excipients of natural origin. | Adopted January 2014 |
| EMEA/CHMP/CVMP/QWP/80360/2014 | Joint CHMP/CVMP template and guidance notes for the Qualified Person's declaration concerning GMP compliance of the active substance and verification of its supply chain. | Adopted March 2014 |
| EMEA/CHMP/CVMP/QWP/63700/2014 | Joint CHMP/CVMP revised guideline on the use of near infrared spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations. | Adopted March 2014<br><br>(End of consultation 31 August 2009) |
| EMA/CHMP/CVMP/QWP/53392/2014 | Joint CHMP/CVMP concept paper for the establishment of a guideline on the selection of sterilisation processes for drug products. | Adopted for consultation, March 2014<br><br>(End of consultation 30 June 2014) |
| [Published on EMA website] | Q&A on limits for unspecified impurities for active substances used in veterinary medicinal products. | Adopted March 2014 |
| [Published on EMA website] | Q&A on the stability of generics versus the innovator product. | Adopted March 2014 |
| [Published on EMA website] | Q&A on the acceptability of two different appearances for a single strength tablet in a single marketing authorisation. | Adopted April 2014 |

| Reference number | Document title | Status |
|---|---|---|
| [Published on EMA website] | Q&A on particles originating from the container-closure system. | Adopted April 2014 |
| EMA/CHMP/CVMP/QWP/136250/2014 | Draft reflection paper on the use of cocrystals and other solid state forms of active substances in medicinal products. | Adopted for consultation, May 2014<br><br>(End of consultation 31 August 2014) |

***CVMP safety***

| Reference number | Document title | Status |
|---|---|---|
| EMA/CVMP/SWP/529692/2013 | Draft concept paper on user risk assessment of topically applied products. | Adopted for consultation, March 2014<br><br>(End consultation 30 June 2014) |

***CVMP efficacy***

| Reference number | Document title | Status |
|---|---|---|
| EMA/CVMP/EWP/513162/2013 | Guideline on for the conduct of efficacy studies for non-steroidal anti-inflammatory drugs (NSAID) (Revised). | Adopted January 2014<br><br>(End of consultation 31 May 2013) |
| EMA/CVMP/EWP/573536/2013 | Draft reflection paper on anthelmintic resistance. | Adopted for consultation, April 2014<br><br>(End of consultation 31 July 2014) |
| [Published on EMA website] | Q&A in respect to the CVMP guideline on pharmaceutical fixed combination products (EMEA/CVMP/83804/2005). | Adopted May 2014 |

***CVMP Pharmacovigilance***

| Reference number | Document title | Status |
|---|---|---|
| EMA/781698/2013 | Public bulletin on veterinary pharmacovigilance for 2013. | Adopted March 2014 |

***Antimicrobials***

| Reference number | Document title | Status |
|---|---|---|
| EMA/CVMP/AWP/119489/2012-Rev.1 | Reflection paper on the use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health (Revised). | Adopted February 2014 |

***General***

| Reference number | Document title | Status |
|---|---|---|
| EMA/CVMP/VICH/758781/2013 | Draft VICH GL53 on electronic exchange of documents: file format requirements – 6 months public consultation. | Adopted for consultation, February 2014<br><br>(End of consultation 20 July 2014) |