10 October 2014
EMA/484743/2014
Veterinary Medicines Division

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

September 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, extensions, variations 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.

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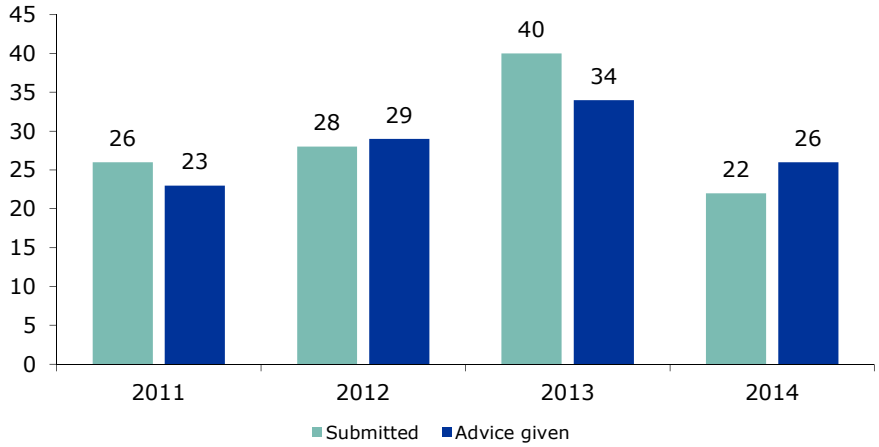
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

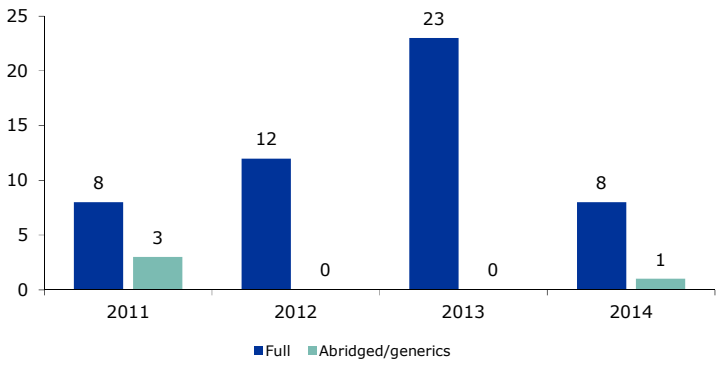
Scientific advice requests				
	2011	2012	2013	2014
Submitted	26	28	40	**22**
Advice given	23	29	34	**26**

Scientific advice requests submitted and andvice given

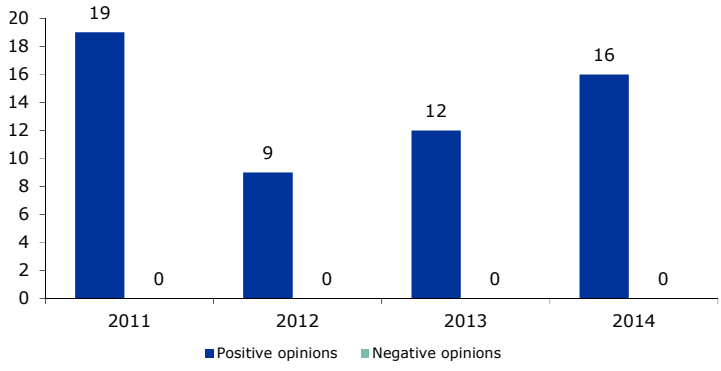


Initial evaluation of marketing authorisation applications				
	2011	2012	2013	2014
Full (submitted)	8	12	23	**8**
Abridged/generics (submitted)	3	0	0	**1**
Withdrawals	0	1	0	**2**
Positive opinions	19	9	12	**16**
Negative opinions	0	0	0	**0**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

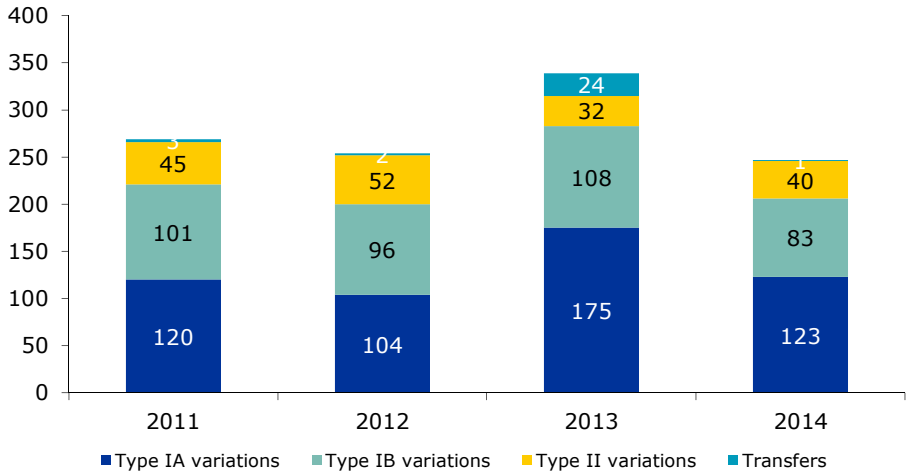


Marketing authorisations				
	2011	2012	2013	2014
Granted	24	8	13	**17**
Withdrawals	1	3	3	**1**
Not renewed	0	0	0	**0**

Extensions — applications				
	2011	2012	2013	2014
Submitted	7	8	5	**5**
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	**123**
Type-IB variations	101	96	108	**83**
Type-II variations	45	52	32	**40**
Transfers	3	2	24	**1**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2011	2012	2013	2014
Submitted	14	10	16	**9**
Positive opinions	12	10	14	**14**
Negative opinions	0	0	0	**0**

Establishment of MRLs for new substances — applications				
	2011	2012	2013	2014
Submitted	1	1	6	**4**
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 of MRLs — applications				
	2011	2012	2013	2014
Submitted	8	5	6	**2**
Withdrawals	2	0	0	**0**
Positive opinions [2]	7	8 (2)	4	**7**
Negative opinions	0	0	0	**0**

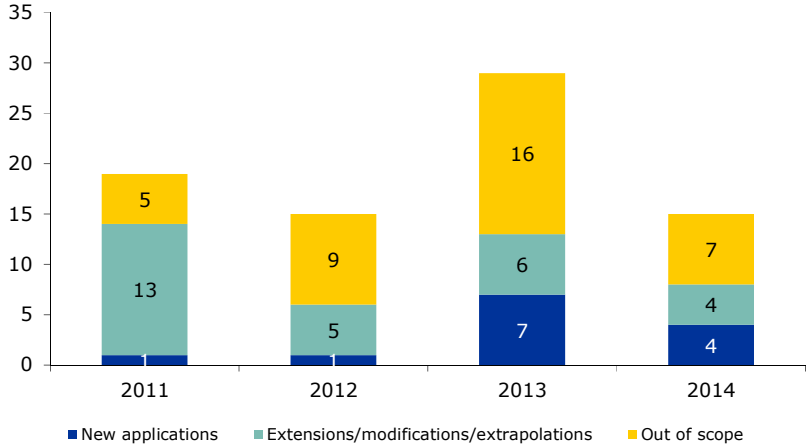
[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances with previously provisional MRLs. Re-examination of opinions are indicated in brackets.

Review of opinions/extrapolations – requests from Commission or Member States				
	2011	2012	2013	2014
Submitted	5	0	1	**2**
Opinion [3]	5	0	4 (3)	**1**

[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.

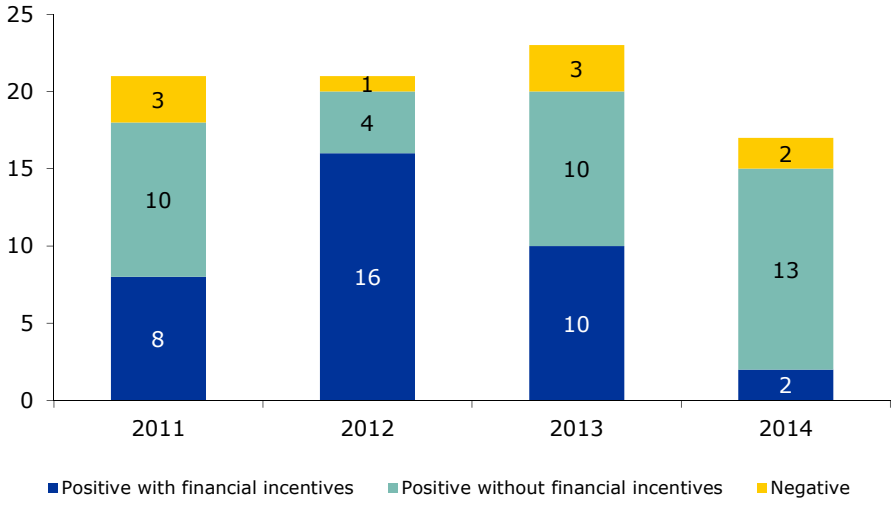
Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2011	2012	2013	2014
Submitted	5	9	16	**7**
Agreed	10	6	9	**7**
Not agreed	0	1	2	**0**
Scientific advice recommended	0	0	6	**1**

MRL-related submissions



MUMS/limited-market classification — requests	2011	2012	2013	2014
Positive with financial incentives	8	16	10	**2**
Positive without financial incentives	10	4	10	**13**
Negative	3	1	3	**2**

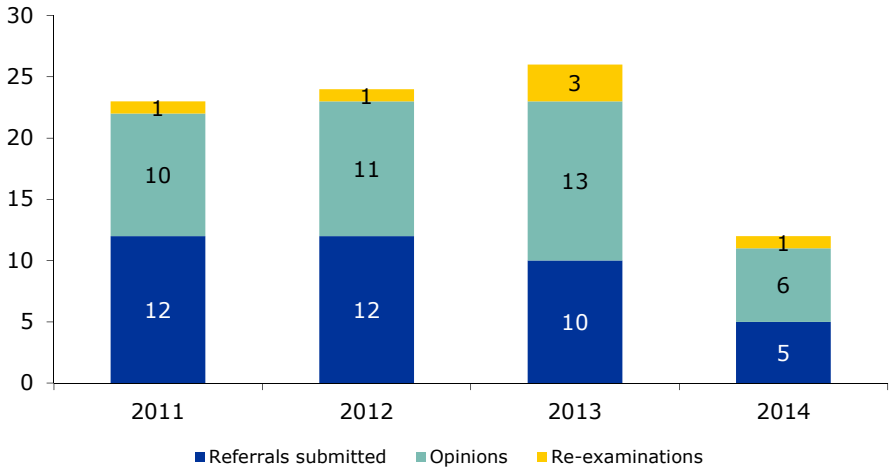
MUMS/limited market classification requests



Arbitrations and referrals	2011	2012	2013	2014
Arbitrations and referrals submitted	12	12	10	**5**
Opinions[3]	10 (1)	11 (1)	13 (3)	**6 (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 • Invented name • INN/Common name	**Marketing authorisation holder**	**Therapeutic area** • Target species • Summary of indication	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Transmission to EC • Decision • Notification • Official Journal
• **Fungitraxx** • Itraconazole	• Avimedical B.V	• Ornamental birds • Treatment of aspergillosis and candidiasis.	• 07/11/2012 • 16/01/2014 • 210 • 225	• 16/01/2014 • 12/02/2014 • 12/03/2014 • 17/03/2014 • C 123 of 25/04/2014
• **Equisolon** • Prednisolone	• LE VET B.V.	• Horse • Alleviation of clinical recurrent airway obstruction (RAO) in combination with environmental control.	• 10/10/2012 • 16/01/2014 • 210 • 253	• 16/01/2014 • 12/02/2014 • 12/03/2014 • 14/03/2014 • C 123 of 25/04/2014
• **Parvoduk** • Muscovy duck parvovirus	• MERIAL	• Muscovy duck • Vaccine against duck parvovirosis and Derzsy's disease.	• 07/11/2012 • 13/02/2014 • 203 • 260	• 13/02/2014 • 10/03/2014 • 11/04/2014 • 15/04/2014 • C 165 of 29/05/2014

Product • Invented name • INN/Common name	**Marketing authorisation holder**	**Therapeutic area** • Target species • Summary of indication	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Transmission to EC • Decision • Notification • Official Journal
• **Versican Plus DHPPi/L4R** • Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus, leptospiras and rabies virus	• Zoetis Belgium SA	• Dog • Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough), parvovirus disease, leptospirosis and rabies.	• 20/03/2013 • 13/03/2014 • 203 • 155	• 13/03/2014 • 09/04/2014 • 07/05/2014 • 09/05/2014 • C 199 of 27/06/2014
• **Versican Plus DHPPi/L4** • Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus and leptospiras	• Zoetis Belgium SA	• Dog • Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough), parvovirus disease and leptospirosis.	• 15/05/2013 • 13/03/2014 • 210 • 92	• 13/03/2014 • 09/04/2014 • 07/05/2014 • 09/05/2014 • C 199 of 27/06/2014
• **Vectra Felis** • Dinotefuran, pyriproxyfen	• Ceva Santé Animale	• Cats • Treatment and prevention of flea infestations.	• 13/12/2012 • 10/04/2014 • 210 • 274	• 10/04/2014 • 06/05/2014 • 06/06/2014 • 11/06/2014 • C 243 of 25/07/2014
• **Versican Plus Pi** • Canine parainfluenza virus	• Zoetis Belgium SA	• Dog • Vaccine against canine parainfluenza virus.	• 12/06/2013 • 08/05/2014 • 210 • 120	• 08/05/2014 • 04/06/2014 • 04/07/2014 • 08/07/2014 • C 290 of 29/08/2014

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Transmission to EC • Decision • Notification • Official Journal
• **Versican Plus DHPPi** • Canine distemper virus, canine adenovirus, canine parvovirus and canine parainfluenza virus	• Zoetis Belgium SA	• Dog • Vaccine against canine distemper, infectious hepatitis, infectious tracheobronchitis (kennel cough) and parvovirus disease.	• 12/06/2013 • 08/05/2014 • 210 • 120	• 08/05/2014 • 04/06/2014 • 04/07/2014 • 08/07/2014 • C 290 of 29/08/2014
• **ERYSENG PARVO** • Porcine parvovirus, erysipelothrix	• Laboratorios HIPRA, S.A.	• Pig • Vaccine against parvovirus disease and swine erysipelas.	• 13/02/2013 • 08/05/2014 • 210 • 239	• 08/05/2014 • 03/06/2014 • 08/07/2014 • 10/07/2014 • C 290 of 29/08/2014
• **ERYSENG** • Erysipelothrix	• Laboratorios HIPRA, S.A.	• Pig • Vaccine against swine erysipelas.	• 13/02/2013 • 08/05/2014 • 210 • 239	• 08/05/2014 • 03/06/2014 • 04/07/2014 • 08/07/2014 • C 290 of 29/08/2014
• **OSURNIA** • Terbinafine, florfenicol and betamethasone acetate	• Novartis Santé Animale S.A.S	• Dog • Treatment of bacterial and fungal external otitis.	• 11/07/2013 • 05/06/2014 • 210 • 120	• 05/06/2014 • 02/07/2014 • 31/07/2014 • 01/08/2014 • C 290 of 29/08/2014
• **Versican Plus L4** • Leptospiras	• Zoetis Belgium SA	• Dog • Vaccine against leptospirosis.	• 10/07/2013 • 05/06/2014 • 210 • 120	• 05/06/2014 • 01/07/2014 • 31/07/2014 • 05/08/2014 • C 290 of 29/08/2014

Product • Invented name • INN/Common name	Marketing authorisation holder	Therapeutic area • Target species • Summary of indication	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Transmission to EC • Decision • Notification • Official Journal
• **Versican Plus Pi/L4** • Canine parainfluenza virus and leptospiras	• Zoetis Belgium SA	• Dog • Vaccine against infectious tracheobronchitis (kennel cough) and leptospirosis.	• 10/07/2013 • 05/06/2014 • 210 • 120	• 05/06/2014 • 01/07/2014 • 31/07/2014 • 04/08/2014 • C 290 of 29/08/2014
• **Versican Plus Pi/L4R** • Canine parainfluenza virus, leptospiras and rabies virus	• Zoetis Belgium SA	• Dog • Vaccine against infectious tracheobronchitis (kennel cough), leptospirosis and rabies.	• 10/07/2013 • 05/06/2014 • 210 • 120	• 05/06/2014 • 01/07/2014 • 31/07/2014 • 04/08/2014 • C 337 of 26/09/2014
• **Nobilis IB Primo QX** • Avian infectious bronchitis virus (IBV)	• Intervet International B.V.	• Chicken • Vaccine against infectious bronchitis.	• 20/03/2013 • 10/07/2014 • 210 • 267	• 10/07/2014 • 06/08/2014 • 04/09/2014
• **Porcilis PCV M Hyo** • Porcine circovirus and Mycoplasma hyopneumoniae	• Intervet International B.V.	• Pig • Vaccine against porcine circovirus disease and mycoplasmosis.	• 13/11/2013 • 11/09/2014 • 210 • 92	• 11/09/2014

CVMP opinions in 2014 on establishment of MRLs

Positive opinions

Product • Substance	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Decision • Notification • Official Journal
• Barium selenate	• All food producing species	• N/a • 10/04/2014 • 130 • N/a	• 11/04/2014
• Clodronic acid (in the form of disodium salt)	• *Equidae*	• 11/12/2013 • 08/05/2014 • 148 • 0	• 14/05/2014
• Eprinomectin	• Ovine, caprine	• N/a • 05/06/2014 • 60 • 0	• 19/06/2014
• Tulathromycin	• Ovine, caprine	• 15/05/2014 • 05/06/2014 • 210 • 176	• 19/06/2014
• Doxycycline	• All food producing species	• 18/09/2013 • 10/07/2014 • 210 • 86	• 23/07/2014
• Gamithromycin	• Porcine	• 14/08/2013 • 10/07/2014 • 210 • 120	• 23/07/2014
• Hexaflumuron	• Fin fish	• 12/06/2014 • 10/07/2014 • 210 • 183	• 23/07/2014
• Methylprednisolone	• *Equidae*	• 05/02/2014 • 10/07/2014 • 155 • 0	• 23/07/2014
• Tulathromycin (modification of ADI and MRLs) After provisional MRLs	• Bovine, porcine	• N/a • 10/07/2014 • 90 • 0	• 23/07/2014

Product • Substance	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Decision • Notification • Official Journal
• Tylvalosin	• Poultry eggs	• 14/11/2013 • 10/07/2014 • 180 • 59	• 23/07/2014

Arbitrations and referrals in 2014

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 35 of Directive 2001/82/EC	• 12/09/2012 • 09/09/2014	• Suanovil 20 and associated names, Captalin and associated names and generic products thereof, including pending applications • Spiramycin
• Referral under Article 34 of Directive 2001/82/EC	• 10/10/2012 • 10/04/2014	• Linco-Spectin 100 and its associated names • Lincomycin, spectinomycin
• Referral under Article 34 of Directive 2001/82/EC	• 07/11/2012 • 09/04/2014	• Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names • Enrofloxacin
• Procedure under Article 30(3) of Regulation 726/2004	• 10/01/2013	• Lidocaine • 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 • Altrenogest
• Referral under Article 35 of Directive 2001/82/EC	• 16/05/2013 • 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 • Enrofloxacin

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 35 of Directive 2001/82/EC	• 06/11/2013 • 08/05/2014	• All veterinary medicinal products containing tylosin to be administered orally via feed or the drinking water to pigs • Tylosin
• Referral under Article 33(4) of Directive 2001/82/EC	• 16/05/2013 • 15/01/2014	• Norbonex 5-mg/ml pour-on solution for beef and dairy cattle • Eprinomectin
• Referral under Article 33(4) Directive 2001/82/EC	• 16/05/2013 • 11/12/2013 • 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 • Fipronil
• Referral under Article 13 of Regulation (EC) No. 1234/2008	• 12/02/2014	• Resflor solution injectable • Florfenicol, flunixin
• Referral under Article 13 of Regulation (EC) No. 1234/2008	• 12/02/2014 • 24/06/2014 (variation application withdrawn by marketing authorisation holder)	• Ubrolexin intramammary suspension for lactating dairy cows • 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 • Gentamicin
• Referral under Article 35 of Directive 2001/82/EC	• 04/06/2014	• All veterinary medicinal products containing colistin to be administered orally • Colistin
• Procedure under Article 30(3) of Regulation 726/2004	• 10/09/2014	• Risks to vultures and other necrophagous bird populations in the European Union in connection with the use of veterinary medicinal products containing the substance diclofenac • Diclofenac

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 (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 (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 (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 (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 (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 (End consultation 30 June 2014)
EMA/CHMP/CVMP/SWP/169430/2012	Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities	Adopted September 2014 (End consultation 30 June 2013)

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 (End of consultation 31 May 2013)
EMA/CVMP/EWP/573536/2013	Draft reflection paper on anthelmintic resistance.	Adopted for consultation, April 2014 (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
EMA/CVMP/EWP/206024/2011	Draft guideline on demonstration of palatability of veterinary medicinal products	Adopted for consultation, July 2014 (End of consultation 31 May 2013)

CVMP pharmacovigilance

Reference number	Document title	Status
EMA/781698/2013	Public bulletin on veterinary pharmacovigilance for 2013.	Adopted March 2014
EMA/CVMP/PhVWP/377918/2014	CVMP combined VeDDRA list of clinical terms for electronic reporting of suspected adverse reactions in animals and humans to veterinary medicinal products.	Adopted July 2014
EMA/CVMP/382972/2014-Rev.7	Revised guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans.	Adopted July 2014

CVMP 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
EMA/CVMP/AWP/158821/2014	Concept paper proposing the development of a reflection paper on the use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, July 2014 (End of consultation 31 October 2014)

CVMP/CHMP application of 3Rs (replacement, refinement and reduction)

Reference number	**Document title**	**Status**
EMA/CHMP/CVMP/JEG-3Rs/94304/2014	Concept paper proposing the development of a guideline on transferring quality control methods validated in collaborative trials to a product/laboratory specific context.	Adopted for consultation, June 2014 (End of consultation 30 September 2014)
EMA/CHMP/CVMP/JEG-3Rs/450091/2012	Draft guideline on regulatory acceptance of 3Rs testing approaches.	Adopted for consultation, September 2014 (End of consultation 31 March 2015)

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 (End of consultation 20 July 2014)