18 January 2016
EMA/844081/2015
Veterinary Medicines Division

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

December 2015

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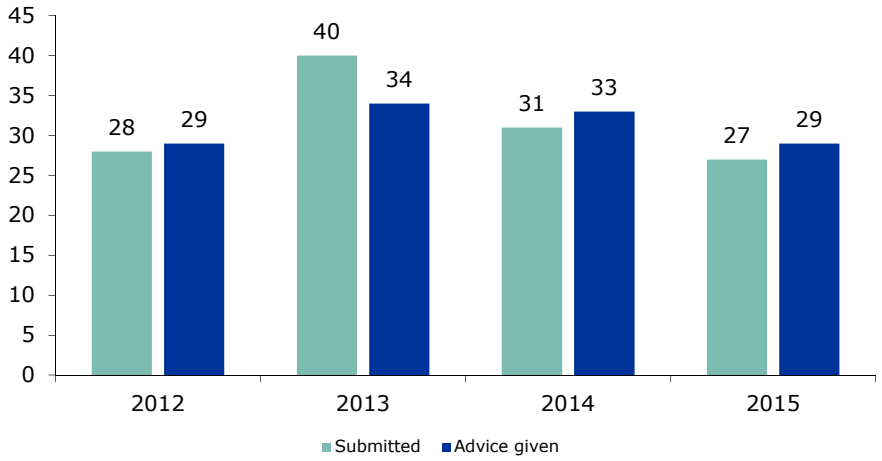
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

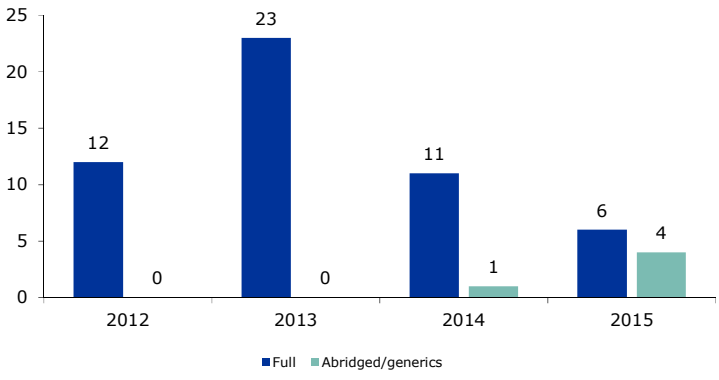
Scientific advice requests	2012	2013	2014	2015
Submitted	28	40	31	**27**
Advice given	29	34	33	**29**

Scientific advice requests submitted and andvice given

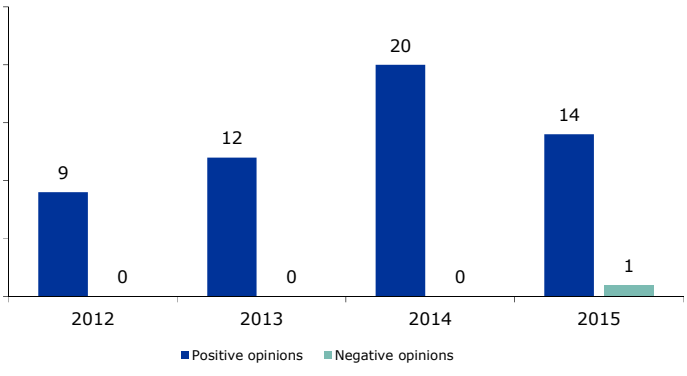


Initial evaluation of marketing authorisation applications	2012	2013	2014	2015
Full (submitted)	12	23	11	**6**
Abridged/generics (submitted)	0	0	1	**4**
Withdrawals	1	0	3	**0**
Positive opinions	9	12	20	**14**
Negative opinions	0	0	0	**1**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

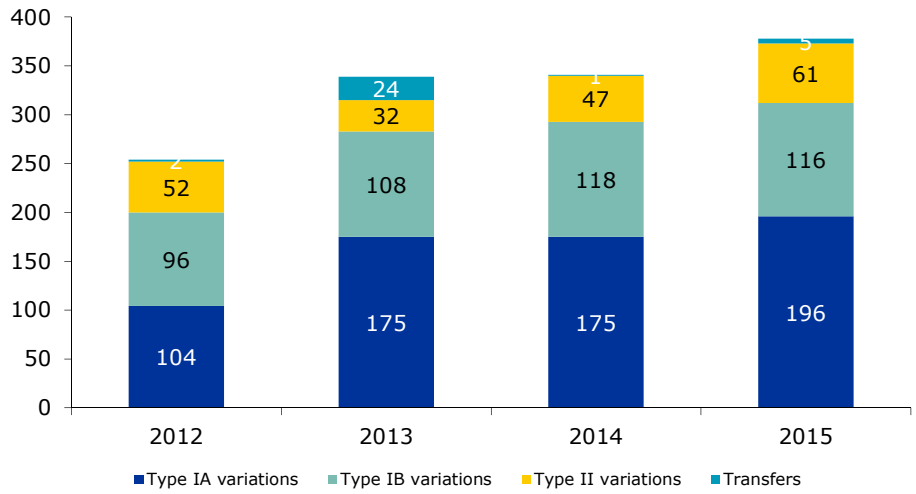


Marketing authorisations				
	2012	2013	2014	2015
Granted	8	13	19	**17**
Withdrawals	3	3	1	**3**
Refusal	0	0	0	**1**
Not renewed	0	0	0	**0**

Extensions — applications				
	2012	2013	2014	2015
Submitted	8	5	6	**3**
Withdrawals	1	0	1	**0**
Positive opinions	5	9	2	**6**
Negative opinions	0	0	0	**1**

Variations — applications submitted				
	2012	2013	2014	2015
Type-IA variations	104	175	175	**196**
Type-IB variations	96	108	118	**116**
Type-II variations	52	32	47	**61**
Transfers	2	24	1	**5**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2012	2013	2014	2015
Submitted	10	16	10	**24**
Positive opinions	10	14	15	**19**
Negative opinions	0	0	0	**0**

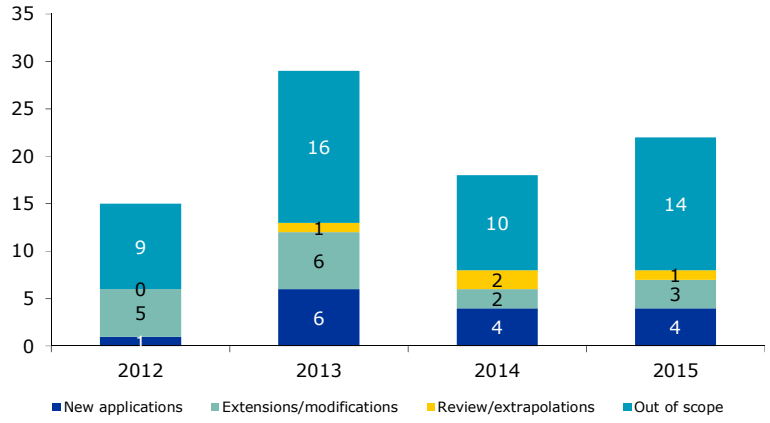
Establishment of MRLs for new substances[1] — applications				
	2012	2013	2014	2015
Submitted	1	6	4	**4**
Withdrawals	1	1	0	**1**
Positive opinions [2,3]	1	4	4	**3(1)**
Negative opinions	0	0	0	**0**

Extensions/modifications of MRLs[4] — applications				
	2012	2013	2014	2015
Submitted	5	6	2	**3**
Withdrawals	0	0	0	**0**
Positive opinions [2,3]	8 (2)	4	8	**2**
Negative opinions	0	0	0	**0**

Review of opinions/extrapolations of MRLs[5] – requests from Commission or Member States				
	2012	2013	2014	2015
Submitted	0	1	2	**1**
Opinion [2]	0	4	2	**3**

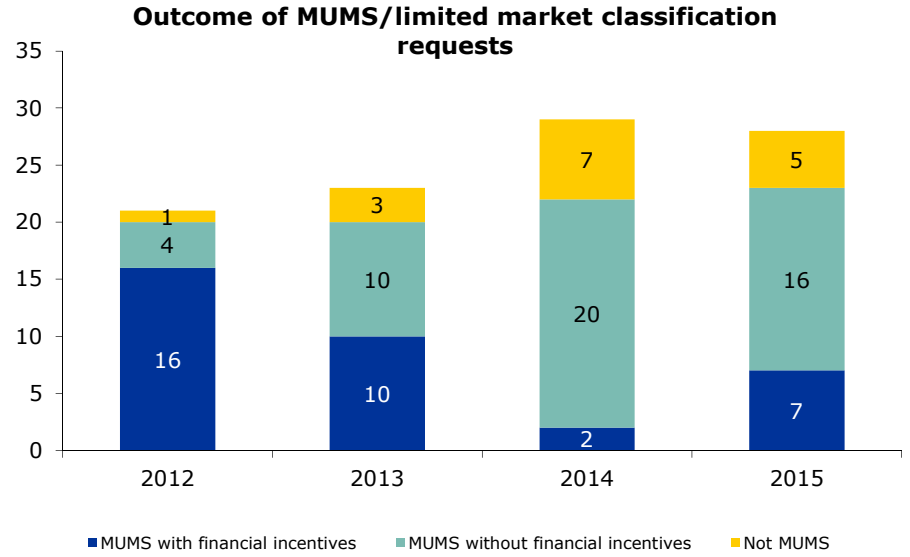
Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2012	2013	2014	2015
Submitted	9	16	10	**14**
Agreed	6	9	9	**18**
Not agreed	1	2	1	**2**
Scientific advice recommended	0	6	1	**1**

MRL-related submissions



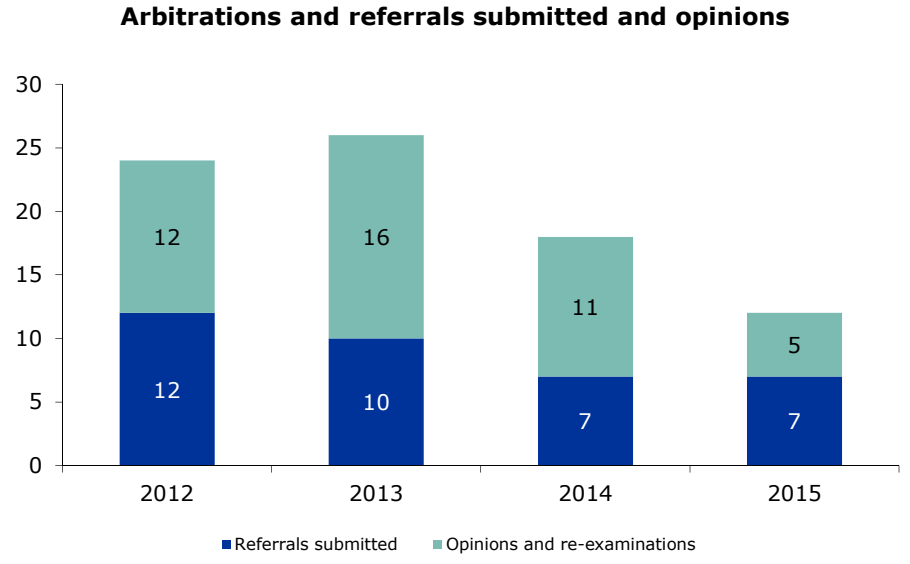
[1] Establishment of MRLs for new substances under article 3 of Regulation (EC) No 470/2009.
[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.
[3] Re-examinations of opinions are indicated in brackets.
[4] Extension or modification of MRLs under article 3 of Regulation (EC) No 470/2009.
[5] Review of opinions under article 11 of Regulation (EC) No 470/2009 or requests under article 27 of Regulation (EC) No 470/2009.

MUMS/limited market classification requests — outcome				
	2012	2013	2014	2015
MUMS/limited market with financial incentives	16	10	2	**7**
MUMS/limited market without financial incentives	4	10	20	**16**
Not MUMS/limited market	1	3	7	**5**



Arbitrations and referrals				
	2012	2013	2014	2015
Arbitrations and referrals submitted	12	10	7	**7**
Opinions[6]	11 (1)	13 (3)	10 (1)	**5**

[6] Re-examination of opinions in brackets.



CVMP opinions in 2015 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
• **Coliprotec F4** • Porcine post-weaning diarrhoea vaccine (live)	• Prevtec Microbia GmbH	• Pig • Vaccine against post-weaning diarrhoea	• 12/03/2014 • 15/01/2015 • 210 • 99	• 15/01/2015 • 11/02/2015 • 16/03/2015 • 18/03/2015 • C 148 of 05/05/2015
• **Sileo** • Dexmedetomidine hydrochloride	• Orion Corporation	• Dog • Alleviation of acute anxiety and fear associated with noise	• 16/10/2013 • 10/04/2015 • 210 • 331	• 10/04/2015 • 07/05/2015 • 10/06/2015 • 12/06/2015 • C 252 of 31/07/2015
• **Innovax-ILT** • Chicken infectious laryngotracheitis and Marek's disease vaccine (live)	• Intervet International B.V.	• Chicken • Vaccine against infectious laryngotracheitis and Marek's disease	• 12/03/2014 • 07/05/2015 • 210 • 211	• 07/05/2015 • 03/06/2015 • 03/07/2015 • 07/07/2015 • C 285 of 28/08/2015
• **Canigen L4** • Canine leptospira vaccine (live)	• Intervet International B.V.	• Dog • Vaccine for the active immunisation of dogs against Leishmania	• 12/01/2015 • 07/05/2015 • 89 • 26	• 07/05/2015 • 02/06/2015 • 03/07/2015 • 07/07/2015 • C 285 of 28/08/2015
• **UpCard** • Torasemide	• Vétoquinol SA	• Dog • Congestive heart failure	• 12/03/2014 • 04/06/2015 • 210 • 239	• 04/06/2015 • 01/07/2015 • 31/07/2015 • 04/08/2015 • C 285 of 28/08/2015
• **FORTEKOR PLUS** • Pimobendan/Benazepril hydrochloride	• Elanco Europe Ltd	• Dog • Congestive heart failure	• 11/12/2013 • 09/07/2015 • 210 • 365	• 09/07/2015 • 05/08/2015 • 08/09/2015 • 10/09/2015 C 361 of 30/10/2015

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
• **PORCILIS PCV ID** • Porcine circovirus vaccine (inactivated)	• Intervet International B.V.	• Pig • Vaccine against porcine circovirus type 2 infection	• 13/08/2014 • 09/07/2015 • 210 • 120	• 09/07/2015 • 31/07/2015 • 28/08/2015 • 01/09/2015 • C 318 of 25/09/2015
• **Vectormune ND** • Newcastle disease and Marek's disease vaccine (live)	• CEVA-Phylaxia Veterinary Biologicals Co. Ltd.	• Chicken • Vaccine against Newcastle disease and Marek's disease	• 14/05/2014 • 09/07/2015 • 210 • 211	• 09/07/2015 • 04/08/2015 • 08/09/2015 • 10/09/2015 • C 361 of 30/10/2015
• **Novaquin** • Meloxicam	• Le Vet Beheer B.V.	• Horse • Alleviation of inflammation and relief of pain in acute and chronic musculo-skeletal disorders	• 13/03/2014 • 09/07/2015 • 210 • 274	• 09/07/2015 • 05/08/2015 • 08/09/2015 • 10/09/2015 • C 361 of 30/10/2015
• **Zycortal** • Desoxycortone Pivalate	• Dechra Limited	• Dog • Replacement therapy for mineralocorticoid deficiency with primary hypoadrenocorticism (Addison's disease)	• 14/05/2014 • 10/09/2015 • 210 • 274	• 10/09/2015 • 07/10/2015 • 06/11/2015 • 10/11/2015 • C 439 of 30/12/2015
• **Simparica** • Sarolaner	• Zoetis Belgium SA	• Dog • Treatment of fleas, ticks and sarcoptic mange	• 11/12/2014 • 10/09/2015 • 210 • 63	• 10/09/2015 • 07/10/2015 • 06/11/2015 • 10/11/2015 • C 439 of 30/12/2015

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
• **Suvaxyn Circo+MH RTU** • Mycoplasma hyopneumoniae (inactivated) and Porcine Circovirus vaccine (inactivated)	• Zoetis Belgium SA	• Pig • Vaccine against porcine circovirus type 2 and Mycoplasma hyopneumoniae infection	• 15/10/2014 • 10/09/2015 • 210 • 120	• 10/09/2015 • 07/10/2015 • 06/11/2015 • 10/11/2015 • C 439 of 30/12/2015
• **Velactis** • Cabergoline	• CEVA Santé Animale	• Dairy cow • Prevention of intra-mammary infections; reduction in milk leakage; reduction in discomfort due to a reduction in udder engorgement and udder pressure, in relation to the dry period	• 18/09/2013 • 08/10/2015 • 210 • 540	• 08/10/2015 • 04/11/2015 • 09/12/2015
• **Imrestor** • Pegbovigrastim	• Eli Lilly and Company Limited	• Dairy cattle, Heifer • Reduction in the risk of clinical mastitis	• 17/09/2014 • 08/10/2015 • 210 • 176	• 08/10/2015 • 04/11/2015 • 09/12/2015

CVMP opinions in 2015 on establishment of MRLs

Positive opinions

Product • Substance	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop • Re-examination	**European Commission** • Opinion received • Regulation • Official Journal
• Sisapronil	• Bovine, caprine	• 12/12/2013 • 15/01/2015 • 210 • 190 • 07/05/2015	• 11/05/2015 • 2015/2062 • L 301 of 18/11/2015
• Diethylene glycol monoethyl ether	• All food producing species	• 17/09/2014 • 12/02/2015 • 148 • 0	• 16/02/2015 • 2015/1820 • L265 of 10/10/2015
• Diflubenzuron	• *Salmonidae*	• N/a • 07/05/2015 • 202 • 168	• 07/05/2015
• Purified semi-solid extract from *Humulus lupulus L.* containing approximately 48% of beta acids (as potassium salts)	• Bees	• 05/02/2014 • 07/05/2015 • 210 • 246	• 11/05/2015
• Gentamicin	• All mammalian food producing species and fin fish	• N/a • 08/10/2015 • 102 • 0	• 08/10/2015
• Rafoxanide	• Bovine and ovine milk	• N/a • 06/11/2015 • N/a • 0	• 06/11/2015 • 681/2014 • L 182 of 10/07/2015
• Copper carbonate	• All food producing species	• 09/07/2015 • 10/12/2015 • 158 • 0	• 11/12/2015
• Eprinomectin (after provisional MRLs)	• All ruminants	• N/a • 10/12/2015 • 90 • 0	• 11/12/2015

Arbitrations and referrals in 2015

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Procedure under Article 30(3) of Regulation 726/2004	• 10/01/2013 • 10/04/2015	• Not applicable • 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 33(4) Directive 2001/82/EC	• 08/10/2014 • 06/05/2015	• Gutal 1000 g/kg premix for medicated feeding stuff for pigs • Zinc oxide
• Procedure under Article 33(4) of Directive 2001/82/EC	• 05/11/2014 • 03/06/2015	• Coglapix vakcina A.U.V. suspension for injection for pigs • *Actinobacillus pleuropneumoniae* strains serotype 1 and 2
• Referral under Article 35 of Directive 2001/82/EC	• 06/05/2015	• All veterinary medicinal products containing a combination of lincomycin and spectinomycin to be administered orally to pigs and/or poultry • Lincomycin and spectinomycin
• Referral under Article 35 of Directive 2001/82/EC	• 06/05/2015	• All veterinary medicinal products containing colistin in combination with other antimicrobial substances to be administered orally • Colistin in combination with other antimicrobial substances
• Referral under Article 33(4) Directive 2001/82/EC	• 03/06/2015 • 04/11/2015	• Solamocta 697 mg/g powder for use in drinking water for chickens, ducks and turkeys • Amoxicillin
• Procedure under Article 78 of Directive 2001/82/EC	• 08/07/2015 • 08/10/2015	• Closamectin pour-on solution and associated names • Closantel and ivermectin
• Referral under Article 34 of Directive 2001/82/EC	• 09/09/2015	• Denagard 45% and associated names • Tiamulin hydrogen fumarate
• Referral under Article 33(4) Directive 2001/82/EC	• 07/10/2015	• CattleMarker IBR Inactivated emulsion for injection for cattle • Infectious bovine rhinotracheitis (IBR) vaccine
• Referral under Article 35 of Directive 2001/82/EC	• 05/11/2015	• All veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses

Guidelines and working documents in 2015

CVMP quality

Reference number	Document title	Status
[Published on EMA website after adoption at CHMP]	Question and Answer document on plastic containers for eye drops.	Adopted February 2015
EMA/CHMP/CVMP/QWP/284008/2015	Reflection paper on the use of cocrystals of active substances in medicinal products	Adopted June 2015
EMA/CVMP/QWP/360463/2015	Concept paper on the need for revision of the veterinary note of guidance on manufacture of the finished dosage form	Adopted for consultation July 2015 (End of consultation 31 October 2015)
EMA/CVMP/QWP/107359/2015	Concept paper on the need for a single veterinary note for guidance on the chemistry of active substances	Adopted for consultation July 2015 (End of consultation 31 October 2015)
[Published on EMA website after adoption at CHMP]	Question and Answer on the use of powders and granules in medicinal products composed of 100% active substance.	Adopted December 2015

CVMP safety

Reference number	Document title	Status
EMA/CVMP/90250/2010	Guideline on risk characterisation and assessment of MRLs for biocides used in animal husbandry.	Adopted January 2015
EMA/CVMP/VICH/463199/2009	VICH GL48(R): Revised guideline on Studies to Evaluate the Metabolism and Residues Kinetics of Veterinary Drugs in Human Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods.	Adopted February 2015
EMA/CVMP/VICH/463202/2009	VICH GL49(R): Revised guideline on Studies to Evaluate the Metabolism and Residues Kinetics of Veterinary Drugs in Human Food-producing Animals: Validation of Analytical Methods used in Residue Depletion Studies.	Adopted February 2015

Reference number	Document title	Status
EMA/CVMP/VICH/699251/2010	VICH GL54: Guideline on studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD), for release for public consultation in the EU at step 4 of the VICH process	Adopted March 2015

CVMP efficacy

Reference number	Document title	Status
EMEA/CVMP/EWP/005/2000-Rev.3	Revised guideline for the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in dogs and cats.	Adopted for consultation March 2015 (End of consultation, 30 September 2015)

CVMP pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/390033/2014	Reflection paper on promotion of pharmacovigilance reporting.	Adopted March 2015
EMA/CVMP/PhVWP/901279/2011	Recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products	Adopted by CVMP in April and by HMA in May 2015
EMA/CVMP/90241/2009	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2015
EMA/CVMP/PhVWP/288284/2007	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2015
EMA/CVMP/PhVWP/590073/2015	Concept paper on revision of the recommendation for the basic surveillance of data contained in EudraVigilance Veterinary	Adopted for consultation November 2015 (End of consultation, 29 February 2016)
EMA/CVMP/PhVWP/145186/2013-Rev1	Revised Questions and Answers on adverse event reporting	Adopted December 2015

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/AWP/401740/2013	Reflection paper on the risk of antimicrobial resistance transfer from companion animals.	Adopted January 2015
EMA/CVMP/EWP/261180/2012	Revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances.	Adopted for consultation February 2015 (End of consultation, 31 May 2015)
EMA/CVMP/AWP/706442/2013	Draft new guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals.	Adopted for consultation February 2015 (End of consultation, 31 August 2015)
EMA/CVMP/AWP/37203/2015	Concept paper for the development of a reflection paper on the use of extended-spectrum penicillins in animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation July 2015 (End of consultation, 31 October 2015)
EMA/CVMP/209189/2015	CVMP Strategy on Antimicrobials 2016-2020	Adopted for consultation November 2015 (End of consultation, 29 February 2016)

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/205351/2006-Rev.1	Draft revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus (BVDV).	Adopted for consultation January 2015 (End of consultation, 30 April 2015)
EMA/CVMP/IWP/206555/2010-Rev.1	Draft revised guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted for consultation July 2015 (End of consultation, 31 January 2016)
EMA/CVMP/IWP/251741/2015	Draft reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds	Adopted for consultation July 2015 (End of consultation, 31

Reference number	Document title	Status
	used for the production of immunological veterinary medicinal products	January 2016)
EMA/CVMP/IWP/351882/2015	Concept paper on requirements for the production and control of allergen products for use in animals	Adopted for consultation September 2015 (End of consultation, 31 December 2015)
EMA/CVMP/IWP/205351/2006-Rev.1	Revised guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea virus (BVDV)	Adopted September 2015
EMA/CVMP/IWP/37924/2014	Reflection paper on the use of heat treatment to inactivate endogenous retroviruses in live immunological veterinary medicinal products	Adopted September 2015
EMA/CVMP/IWP/37620/2014	Reflection paper on the replacement of cell lines used for the production of immunological veterinary medicinal products	Adopted September 2015
EMA/CVMP/IWP/309514/2015	Concept paper on guidance on statistical principles for clinical trials for veterinary immunological medicinal products	Adopted for consultation December 2015 (End of consultation 31 March 2016)

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/349254/2014	Draft reflection paper on poorly extractable and/or non-radiolabelled substances.	Adopted for consultation March 2015 (End of consultation, 31 August 2015)
EMA/CVMP/ERA/698394/2014	Concept paper on the testing strategy and risk assessment for plants in Phase II of the environmental risk assessment for veterinary medicinal products	Adopted for consultation June 2015 (End of consultation, 30 September 2015)
EMA/CVMP/ERA/52740/2012	Guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal	Adopted September 2015

Reference number	Document title	Status
	products.	

General

Reference number	Document title	Status
EMA/CVMP/VICH/758781/2013	VICH GL53: Guideline on electronic exchange of documents: electronic file formats, for implementation.	Adopted March 2015
EMA/CVMP/VICH/751935/2013	VICH GL52: Bioequivalence: blood level bioequivalence study	Adopted September 2015
EMA/CVMP/450781/2015	Guideline on the principles for preparing assessment reports for veterinary medicinal products	Adopted December 2015
EMA/CVMP/550607/2015	Question and Answer document on solvents in the centralised procedure.	Adopted for consultation December 2015 (End of consultation 31 March 2016)