8 April 2014
EMA/156949/2014
Veterinary Medicines Division

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

March 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.

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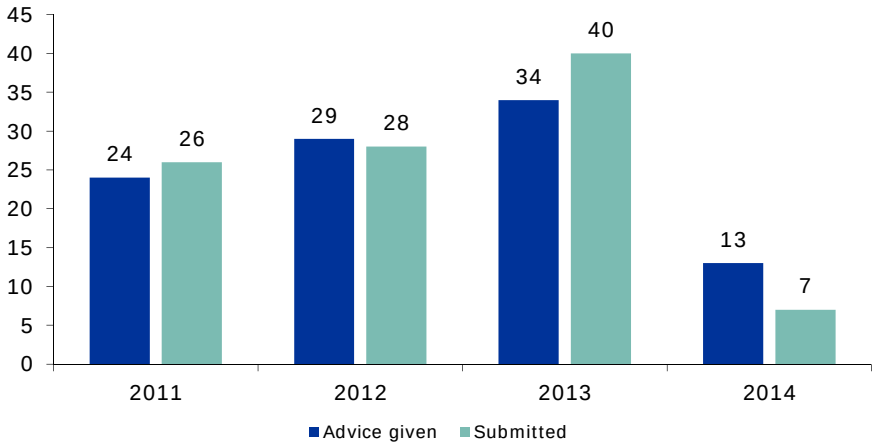
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

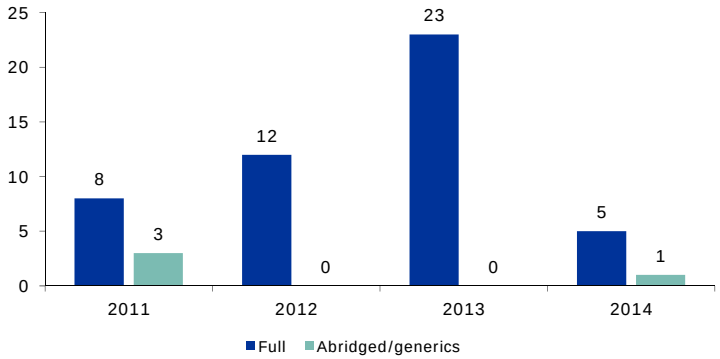
Scientific-advice requests				
	2011	2012	2013	2014
Submitted	26	28	40	**7**
Advice given	24	29	34	**13**

Scientific advice requests sumbmitted and andvice given

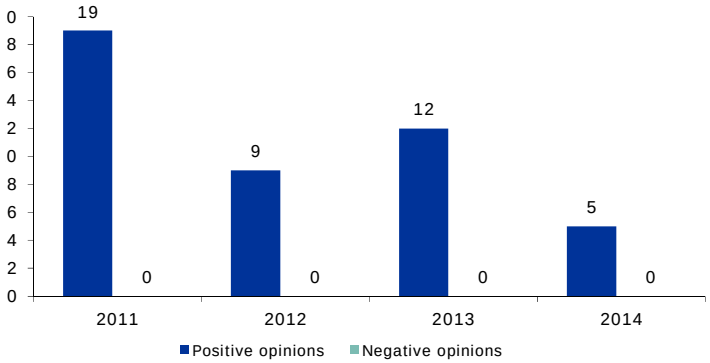


Initial evaluation of marketing-authorisation applications				
	2011	2012	2013	2014
Full (submitted)	8	12	23	**5**
Abridged/generics (submitted)	3	0	0	**1**
Withdrawals	0	1	0	**0**
Positive opinions	19	9	12	**5**
Negative opinions	0	0	0	**0**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

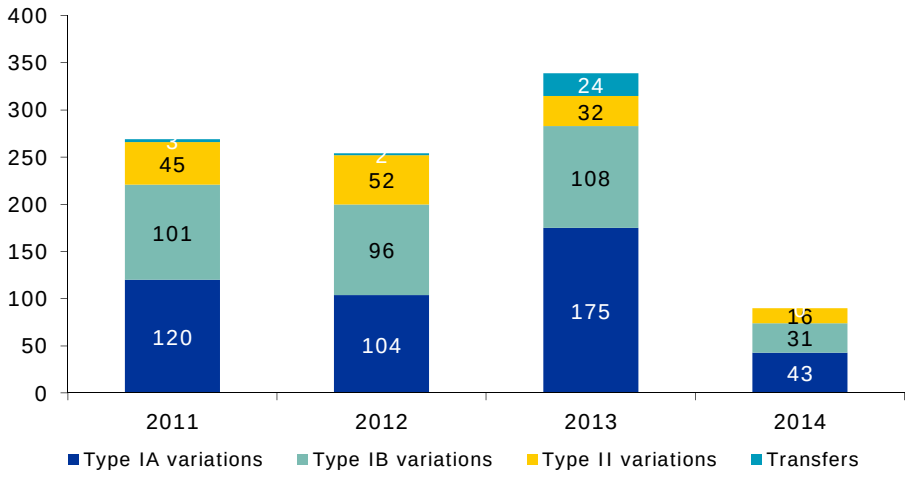


Marketing authorisations				
	2011	2012	2013	2014
Granted	24	8	13	**3**
Withdrawals	1	3	3	**0**
Not renewed	0	0	0	**0**

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

Variations — applications submitted				
	2011	2012	2013	2014
Type-IA variations	120	104	175	**43**
Type-IB variations	101	96	108	**31**
Type-II variations	45	52	32	**16**
Transfers	3	2	24	**0**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2011	2012	2013	2014
Submitted	14	10	16	**4**
Positive opinions	12	10	14	**4**
Negative opinions	0	0	0	**0**

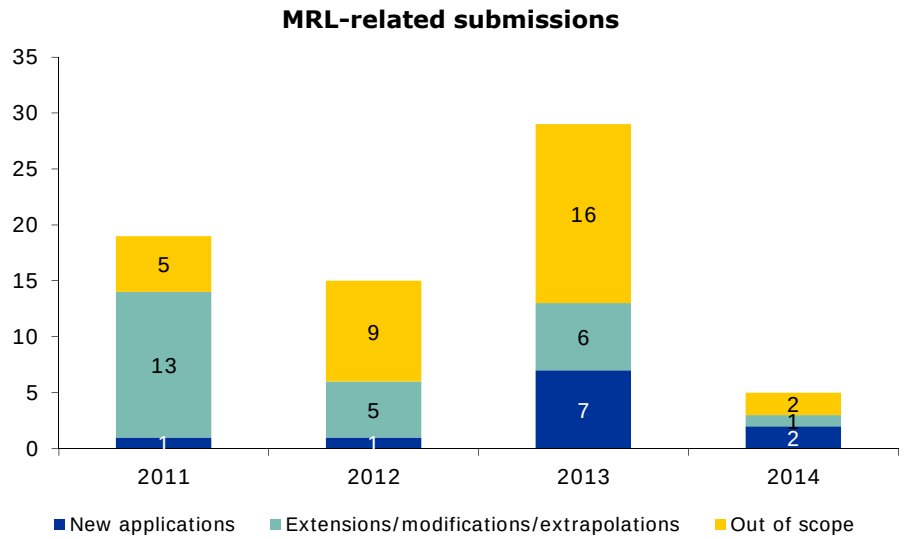
Establishment of MRLs for new substances — applications				
	2011	2012	2013	2014
Submitted	1	1	7	**2**
Withdrawals	0	1	1	**0**
Positive opinions[1]	4	1	4	**0**
Negative opinions	0	0	0	**0**

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

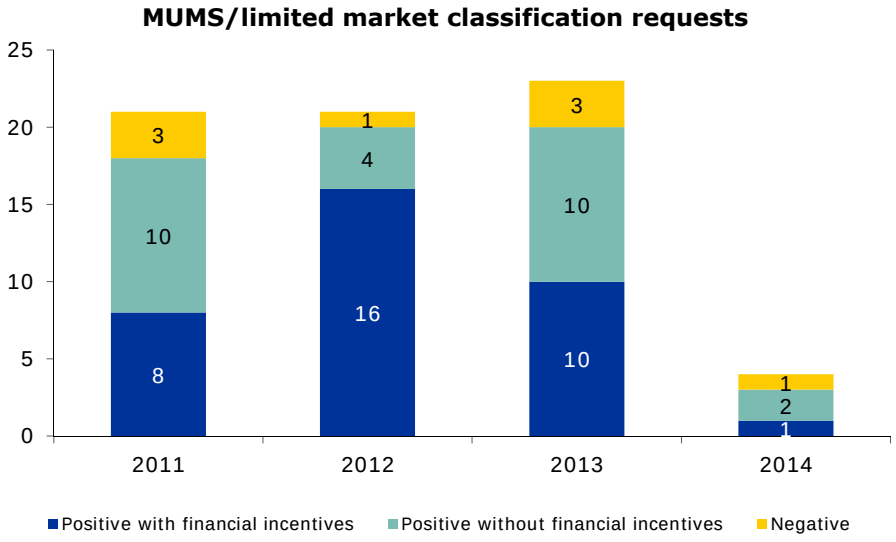
Extensions/modifications/extrapolations of MRLs — applications				
	2011	2012	2013	2014
Submitted	13	5	6	**1**
Withdrawals	2	0	0	**0**
Positive opinions[2]	12	8 (2)	8	**0**
Negative opinions	0	0	0	**0**

[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.

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

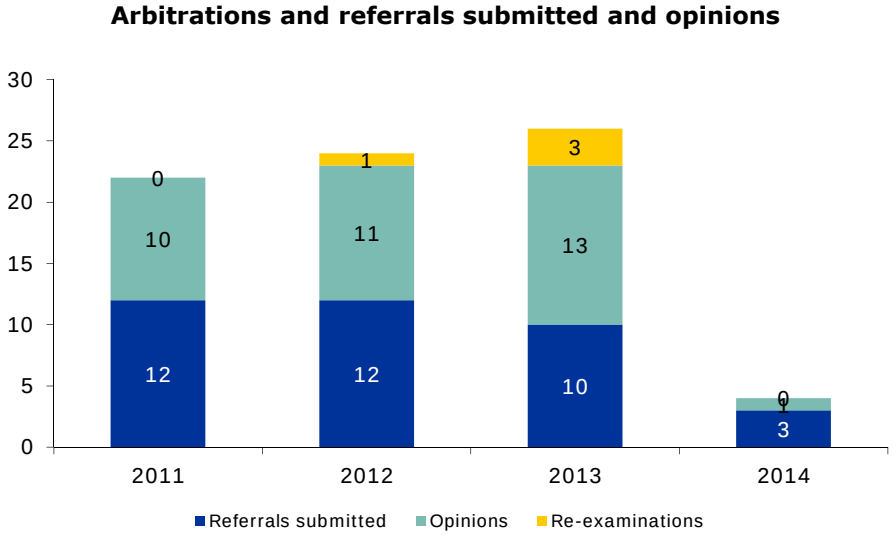


MUMS/limited-market classification — requests	2011	2012	2013	2014
Positive with financial incentives	8	16	10	**1**
Positive without financial incentives	10	4	10	**2**
Negative	3	1	3	**1**



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

[3] Re-examination of opinions in brackets.



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
• **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
• **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
• **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
• **Versican Plus DHPPi/L4** • Canine distemper	• Zoetis Belgium SA	• Dog • Vaccine against canine distemper, infectious hepatitis,	• 15/05/2013 • 13/03/2014 • 210 • 92	• 13/03/2014

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
virus, canine adenovirus, canine parvovirus, canine parainfluenza virus and leptospiras		infectious tracheobronchitis (kennel cough), parvovirus disease and leptospirosis.		

CVMP opinions in 2014 on establishment of MRLs

Positive opinions

Product • Substance • INN/Common name	**Target species**	**EMA/CVMP** • Validation • Opinion • Active time • Clock stop	**European Commission** • Opinion received • Decision • Notification • Official Journal
•	•	•	•

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	• 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	• Linco-Spectin 100 and its associated names • Lincomycin, spectinomycin
• Referral under Article 34 of Directive 2001/82/EC	• 07/11/2012	• Baytril 2.5% injectable, Baytril 5% injectable and Baytril 10% injectable and their associated names • Enrofloxacin
• Referral 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	• 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	• 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 (under re-examination)	• 16/05/2013 • 11/12/2013	• 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	• 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

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

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/529692/2013	Draft concept paper on user risk assessment of topically applied	Adopted for consultation, March 2014

Reference number	Document title	Status
	products	(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 (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

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 (End of consultation 20 July 2014)