17 February 2015
EMA/786165/2014
Veterinary Medicines Division

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

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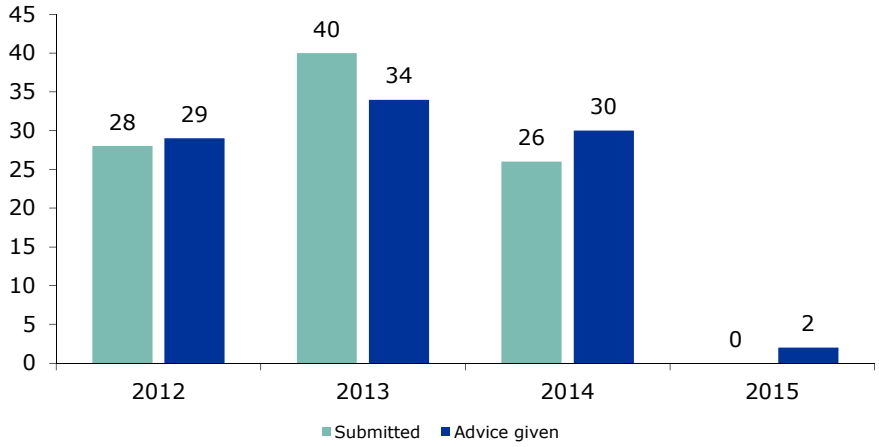
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

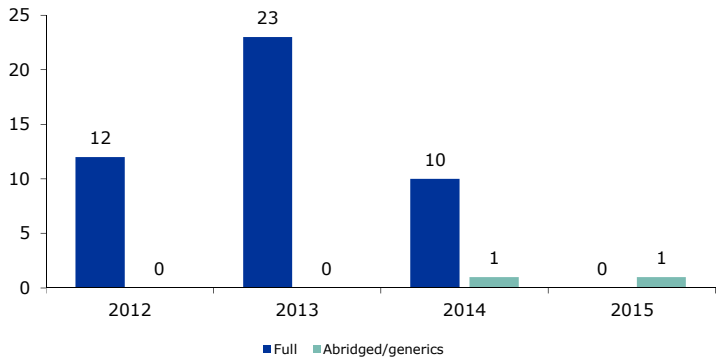
Scientific advice requests				
	2012	2013	2014	2015
Submitted	28	40	31	**0**
Advice given	29	34	33	**2**

Scientific advice requests submitted and andvice given

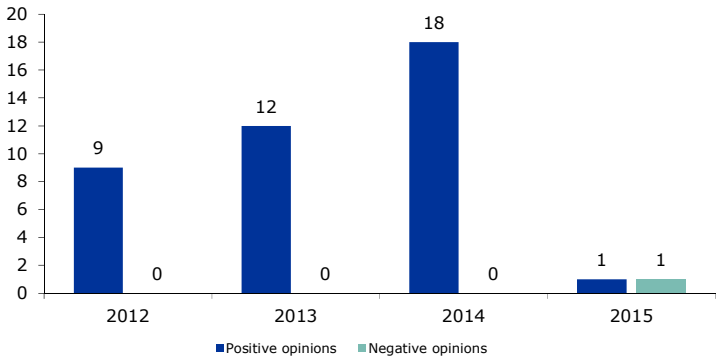


Initial evaluation of marketing authorisation applications				
	2012	2013	2014	2015
Full (submitted)	12	23	11	**0**
Abridged/generics (submitted)	0	0	1	**1**
Withdrawals	1	0	3	**0**
Positive opinions	9	12	20	**1**
Negative opinions	0	0	0	**1**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

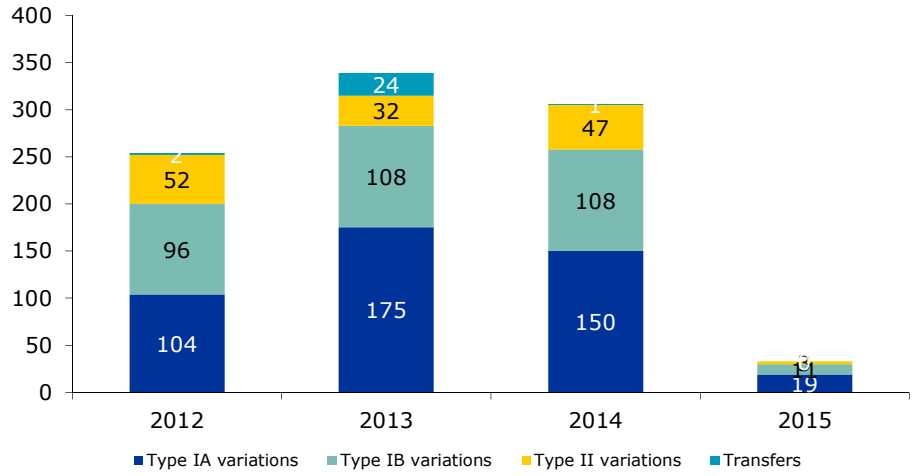


Marketing authorisations				
	2012	2013	2014	2015
Granted	8	13	19	**1**
Withdrawals	3	3	1	**0**
Not renewed	0	0	0	**0**

Extensions — applications				
	2012	2013	2014	2015
Submitted	8	5	6	**1**
Withdrawals	1	0	1	**0**
Positive opinions	10	9	2	**1**
Negative opinions	0	0	0	**0**

Variations — applications submitted				
	2012	2013	2014	2015
Type-IA variations	104	175	175	**19**
Type-IB variations	96	108	118	**11**
Type-II variations	52	32	47	**3**
Transfers	2	24	1	**0**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2012	2013	2014	2015
Submitted	10	16	10	**3**
Positive opinions	10	14	15	**0**
Negative opinions	0	0	0	**0**

Establishment of MRLs for new substances — applications				
	2012	2013	2014	2015
Submitted	1	6	4	**0**
Withdrawals	1	1	0	**0**
Positive opinions [1]	1	4	4	**1**
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				
	2012	2013	2014	2015
Submitted	5	6	2	**0**
Withdrawals	0	0	0	**0**
Positive opinions [2]	8 (2)	4	8	**0**
Negative opinions	0	0	0	**0**

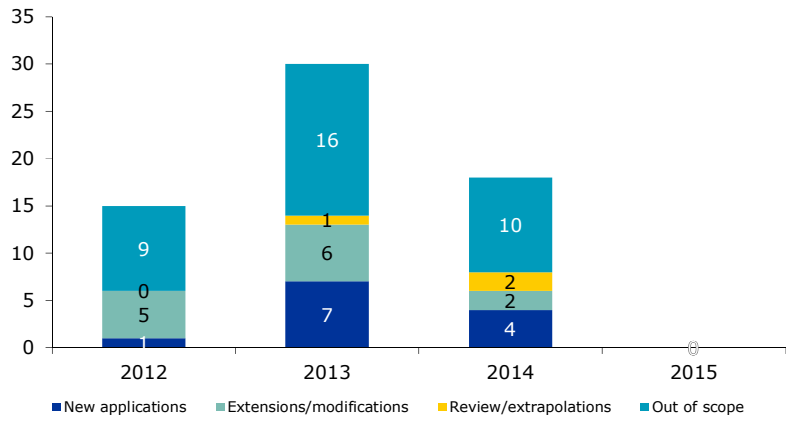
[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances with previously provisional MRLs. Re-examination of opinions are indicated in brackets.

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

[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.

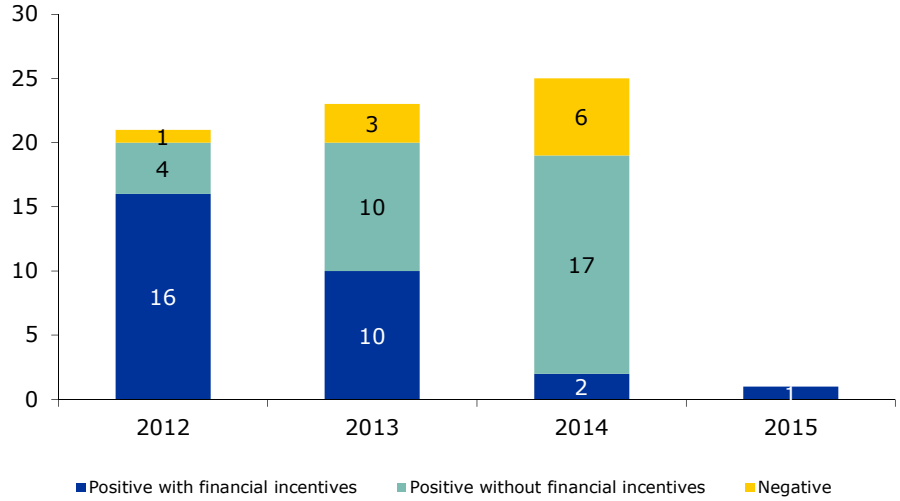
Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2012	2013	2014	2015
Submitted	9	16	10	**0**
Agreed	6	9	9	**1**
Not agreed	1	2	1	**0**
Scientific advice recommended	0	6	1	**0**

MRL-related submissions



MUMS/limited-market classification — requests	2012	2013	2014	2015
Positive with financial incentives	16	10	2	**1**
Positive without financial incentives	4	10	20	**0**
Negative	1	3	7	**0**

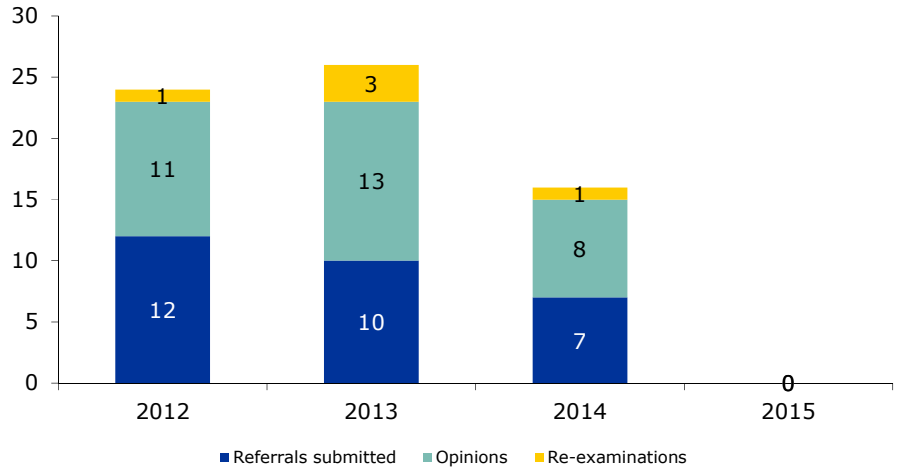
MUMS/limited market classification requests



Arbitrations and referrals	2012	2013	2014	2015
Arbitrations and referrals submitted	12	10	7	**0**
Opinions[3]	11 (1)	13 (3)	10 (1)	**0**

[3] Re-examination of opinions in brackets.

Arbitrations and referrals submitted and opinions



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** • Escherichia coli	• Prevtec Microbia GmbH	• Pig • Vaccine against post-weaning diarrhoea	• 12/03/2014 • 15/01/2015 • 210 • 99	• 15/01/2015

CVMP opinions in 2015 on establishment of MRLs

Positive opinions

Product • Substance	Target species	EMA/CVMP • Validation • Opinion • Active time • Clock stop	European Commission • Opinion received • Regulation • Official Journal
• **Sisapronil**	• Bovine, caprine	• 12/12/2013 • 15/01/2015 • 210 • 190	• 23/01/2015

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	• 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 33(4) Directive 2001/82/EC	• 08/10/2014	• 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	• Coglapix vakcina A.U.V. suspension for injection for pigs • *Actinobacillus pleuropneumoniae* strains serotype 1 and 2

Guidelines and working documents in 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

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

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)