11 May 2016
EMA/246326/2016
Veterinary Medicines Division

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

April 2016

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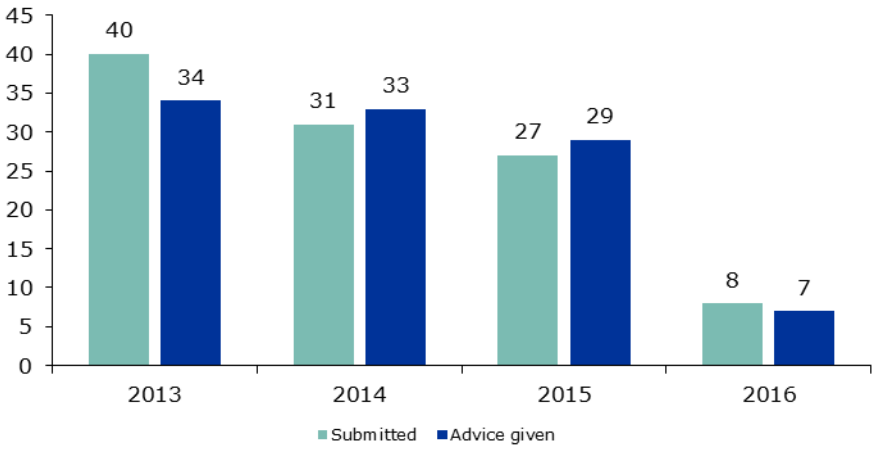
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

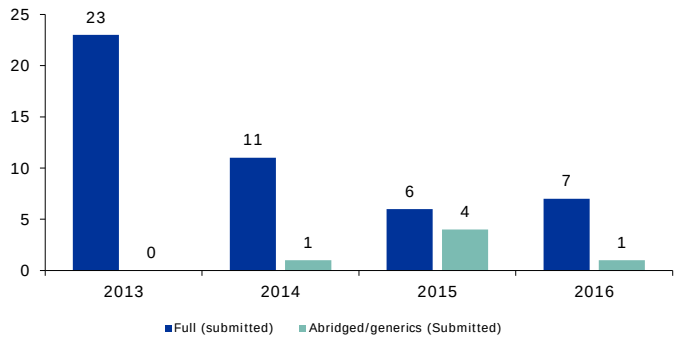
Scientific advice requests				
	2013	2014	2015	2016
Submitted	40	31	27	**8**
Advice given	34	33	29	**7**

Scientific advice requests submitted and andvice given

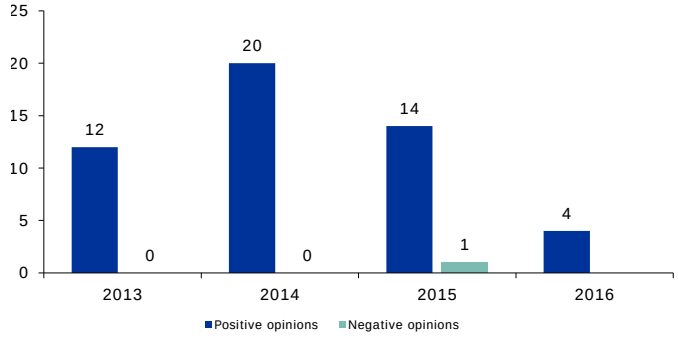


Initial evaluation of marketing authorisation applications				
	2013	2014	2015	2016
Full (submitted)	23	11	6	**7**
Abridged/generics (submitted)	0	1	4	**1**
Withdrawals	0	3	0	**0**
Positive opinions	12	20	14	**4**
Negative opinions	0	0	1	**0**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

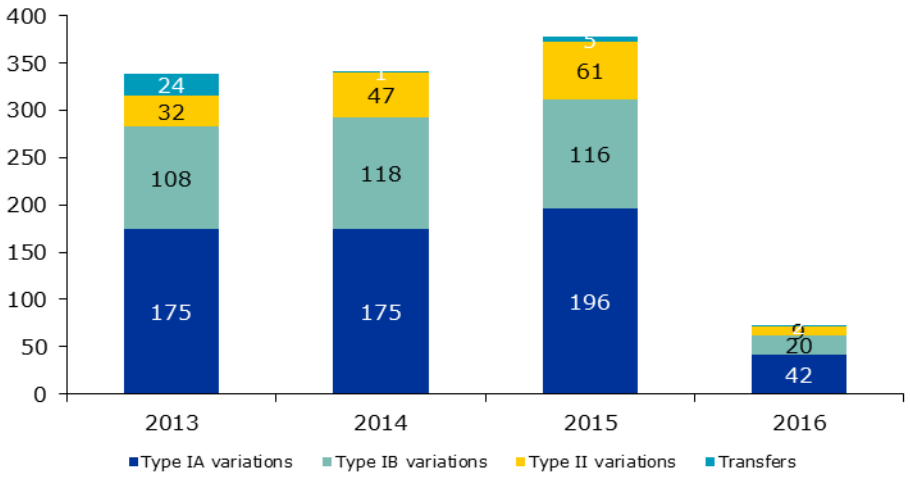


Marketing authorisations				
	2013	2014	2015	2016
Granted	13	19	17	**2**
Withdrawals	3	1	3	**0**
Refusal	0	0	1	**0**
Not renewed	0	0	0	**0**

Extensions — applications				
	2013	2014	2015	2016
Submitted	5	6	3	**1**
Withdrawals	0	1	0	**0**
Positive opinions	9	2	6	**2**
Negative opinions	0	0	1	**0**

Variations — applications submitted				
	2013	2014	2015	2016
Type-IA variations	175	175	196	**42**
Type-IB variations	108	118	116	**20**
Type-II variations	32	47	61	**9**
Transfers	24	1	5	**2**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2013	2014	2015	2016
Submitted	16	10	24	**5**
Positive opinions	14	15	19	**9**
Negative opinions	0	0	0	**0**

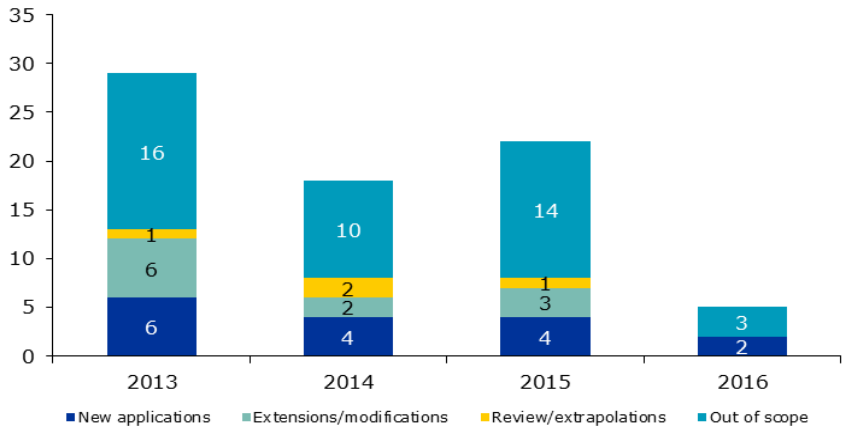
Establishment of MRLs for new substances[1] — applications				
	2013	2014	2015	2016
Submitted	6	4	4	**2**
Withdrawals	1	0	1	**0**
Positive opinions [2,3]	4	4	3(1)	**1**
Negative opinions	0	0	0	**0**

Extensions / modifications of MRLs[4] — applications				
	2013	2014	2015	2016
Submitted	6	2	3	**0**
Withdrawals	0	0	0	**0**
Positive opinions [2]	4	8	2	**0**
Negative opinions	0	0	0	**0**

Review of opinions / extrapolations of MRLs[5] – requests from Commission or Member States				
	2013	2014	2015	2016
Submitted	1	2	1	**0**
Opinion [2]	4	2	3	**0**

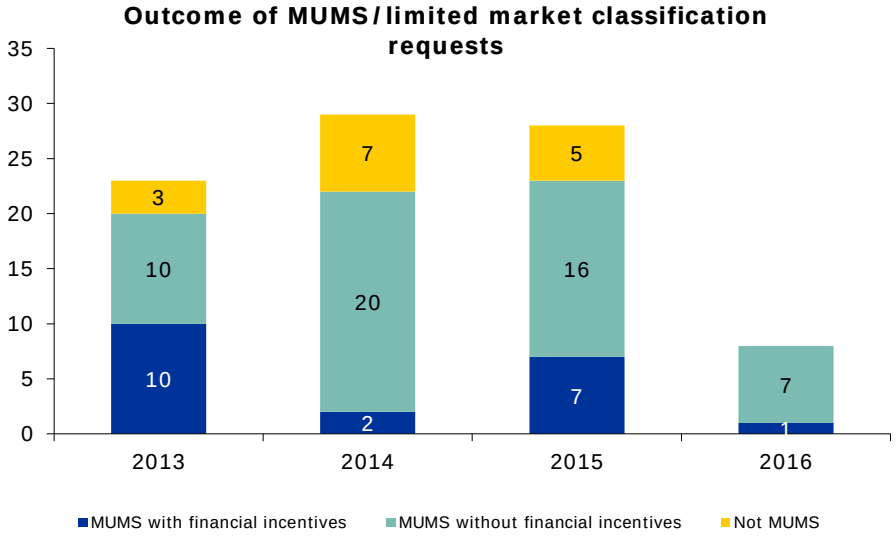
Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2013	2014	2015	2016
Submitted	16	10	14	**4**
Agreed	9	9	18	**3**
Not agreed	2	1	2	**0**
Scientific advice recommended	6	1	1	**0**

MRL-related submissions



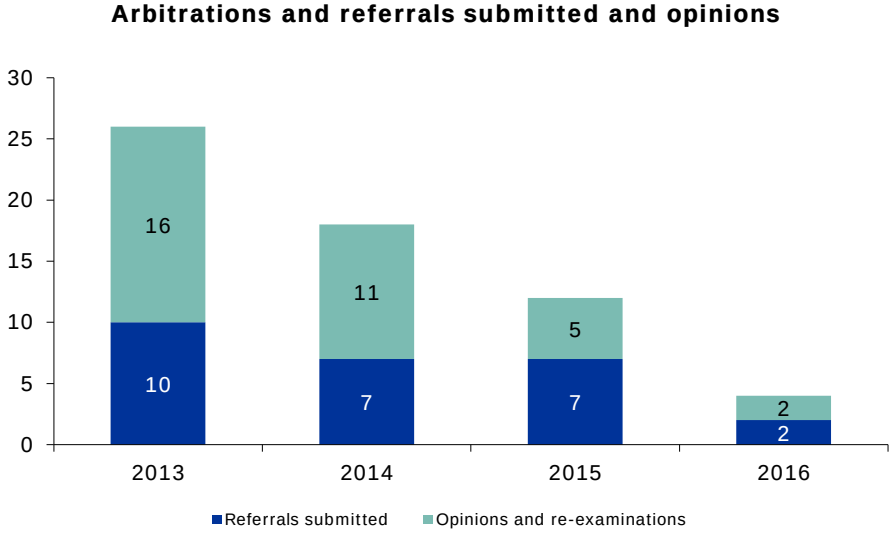
[1] Establishment of MRLs for new substances under article 3 of Regulation (EC) No 470/2009.
[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.
[3] Re-examinations of opinions are indicated in brackets.
[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	2013	2014	2015	2016
MUMS/limited market with financial incentives	10	2	7	**1**
MUMS/limited market without financial incentives	10	20	16	**7**
Not MUMS/limited market	3	7	5	**0**



Arbitrations and referrals	2013	2014	2015	2016
Arbitrations and referrals submitted	10	7	7	**2**
Opinions[6]	13 (3)	10 (1)	5	**2**

[6] Re-examination of opinions in brackets.



CVMP opinions in 2016 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
• Evalon • Coccidiosis vaccine (live) for chickens	• LABORATORIOS HIPRA, S.A.	• Chickens • Active immunisation against coccidiosis	• 04/02/2015 • 18/02/2016 • 210 • 169	• 18/02/2016 • 16/03/2016 • 18/04/2016
• Letifend • Canine leishmaniasis vaccine (recombinant protein)	• Laboratorios LETI, S.L.U.	• Dogs • Immunisation of non-infected dogs against leishmaniasis	• 12/11/2014 • 18/02/2016 • 210 • 253	• 18/02/2014 • 16/03/2016 • 20/04/2016

CVMP opinions in 2016 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
• Hydrocortisone aceponate	• All ruminants and *Equidae*	• 12/03/2014 • 18/02/2016 • 210 • 498 • N/a	• 19/02/2016

Arbitrations and referrals in 2016

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• 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	• 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 • 21/04/2016	• 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 34 of Directive 2001/82/EC	• 09/09/2015	• Denagard 45% and associated names • Tiamulin hydrogen fumarate
• Referral under Article 33(4) of Directive 2001/82/EC	• 07/10/2015 • 17/03/2016	• 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
• Referral under Article 35 of Directive 2001/82/EC	• 20/01/2016	• All veterinary medicinal products containing gentamicin presented as solutions for injection for cattle and pigs
• Referral under Article 35 of Directive 2001/82/EC	• 17/02/2016	• All veterinary medicinal products containing zinc oxide to be administered orally to food producing species

Guidelines and working documents in 2016

CVMP quality

Reference number	Document title	Status
EMA/CVMP/QWP/128710/2004 – Rev.1	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)
EMA/CHMP/CVMP/QWP/850374/2015	Draft guideline on the sterilisation of the medicinal product, active substance, excipient and primary container.	Adopted for consultation February 2016 (End of consultation 13 October 2016)
EMA/CVMP/QWP/3629/2016	Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances	Adopted for consultation February 2016 (End of consultation to be confirmed)
[Published on EMA website]	Questions and Answers (Q&A) on the data requirements for sterilisation processes of primary packaging material subsequently used in an aseptic manufacturing process	Adopted February 2016
[Published on EMA website]	Questions and Answers (Q&A) relating to the SPC guideline for antimicrobials, in regard to suitable pack sizes for antimicrobials	Adopted February 2016
EMEA/CVMP/271/01-Rev.1	Revised note for guidance on limitations to the use of ethylene oxide in the manufacture of medicinal products	Noted March 2016
EMA/CHMP/CVMP/QWP/37330/2016	Draft reflection paper on the dissolution specification for generic oral immediate release products	Adopted for consultation April 2016 (End of consultation to be confirmed)

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/66781/2005 – Rev.1	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)

CVMP efficacy

Reference number	Document title	Status
EMA/CVMP/11490/2016	Draft concept paper for the revision on the guideline for the conduct of pharmacokinetic studies in target animal species (EMEA/CVMP/133/99-Final)	Adopted for consultation January 2016 (End of consultation 31 March 2016)
EMA/CVMP/EWP/117899/2004 – Rev.1)	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)
EMA/CVMP/344/1999-Rev.2	Revised draft guideline on the conduct of efficacy studies for intramammary products for use in cattle	Adopted for second consultation February 2016 (End of consultation 31 May 2016)
CVMP/EWP/573536/2013	Revised reflection paper on anthelmintic resistance	Adopted for second consultation April 2016 (End of consultation 31 July 2016)
EMA/CVMP/EWP/707453/2015	Concept paper for the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2/2007)	Adopted for consultation April 2016 (End of consultation 31 July 2016)

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/627/01-Rev.1	Revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Adopted January 2016

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/123243/2006 – Rev.3).	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)

Reference number	Document title	Status
EMA/CVMP/IWP/867401/2015	Concept paper on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use	Adopted for consultation April 2016 (End of consultation 31 July 2016)

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/448211/2015	Reflection paper on the authorisation of veterinary medicinal products containing (potential) Persistent Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances	Adopted for consultation February 2016 (End of consultation 31 May 2016)
EMA/CVMP/ERA/349254/2014	Reflection paper on poorly extractable and/or non-radiolabelled substances	Adopted March 2016

CVMP novel therapies

Reference number	Document title	Status
EMA/CVMP/ADVENT/226871/2015	Problem statement on monoclonal antibodies intended for veterinary use	Adopted for consultation February 2016 (End of consultation 15 May 2016)
EMA/CVMP/ADVENT/276476/2015	Problem statement on sterility in relation to stem cell products intended for veterinary use	Adopted for consultation February 2016 (End of consultation 15 May 2016)

Replacement, Reduction, Refinement of animal testing (3Rs)

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/164002/2016	Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs	Adopted for consultation April 2016 (End of consultation 31 October 2016)

General

Reference number	Document title	Status
EMA/CVMP/VICH/582610/2009	VICH GL50: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use	Adopted for consultation following the sign-off by the VICH Steering Committee (End of consultation 1 August 2016)
EMA/CVMP/VICH/313610/2013	VICH GL55: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use	Adopted for consultation following the sign-off by the VICH Steering Committee (End of consultation 1 August 2016)