12 April 2017
EMA/177535/2017
Veterinary Medicines Division

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

March 2017

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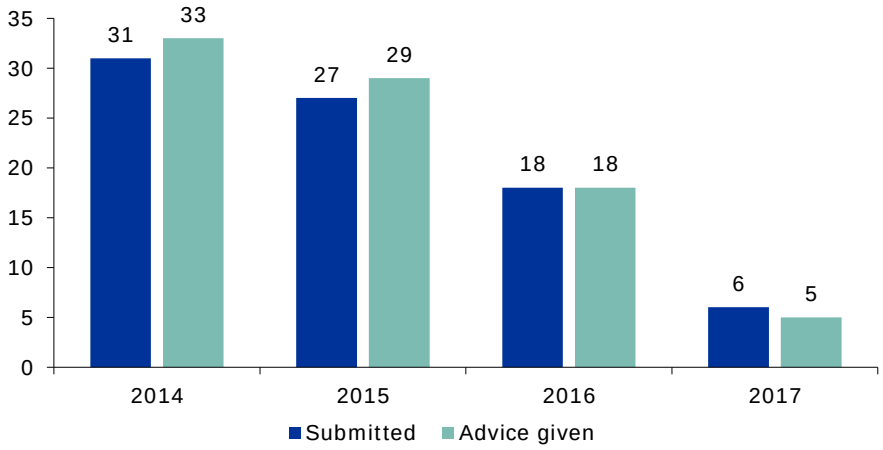
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

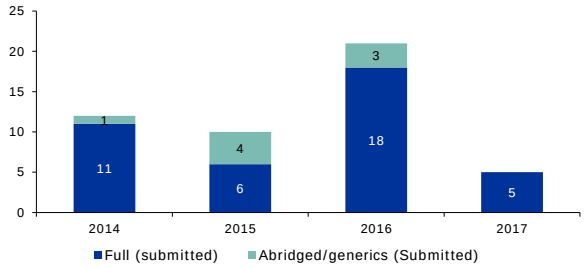
Scientific advice requests	2014	2015	2016	2017
Submitted and validated	31	27	18	**6**
Advice given	33	29	18	**5**

Scientific advice requests submitted and advice given

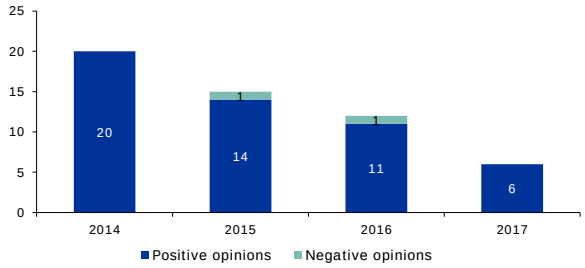


Initial evaluation of marketing authorisation applications	2014	2015	2016	2017
Full (submitted)	11	6	18	**5**
Abridged/generics (submitted)	1	4	3	**0**
Withdrawals	3	0	1	**1**
Positive opinions	20	14	11	**6**
Negative opinions	0	1	1	**0**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

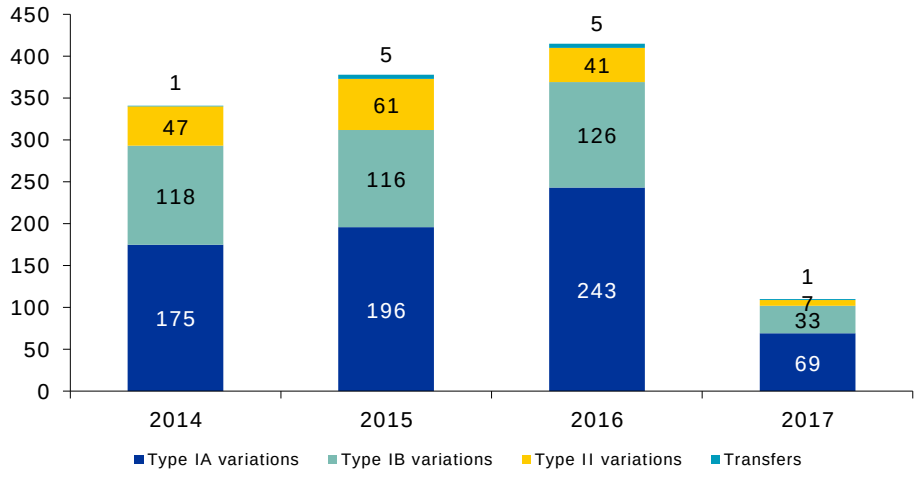


Marketing authorisations				
	2014	2015	2016	2017
Granted	19	17	7	**3**
Withdrawals	1	3	1	**0**
Refusal	0	1	0	**0**
Not renewed	0	0	1	**0**

Extensions — applications				
	2014	2015	2016	2017
Submitted	6	3	3	**0**
Withdrawals	1	0	0	**0**
Positive opinions	2	6	5	**0**
Negative opinions	0	1	0	**0**

Variations — applications submitted				
	2014	2015	2016	
Type-IA variations	175	196	243	**69**
Type-IB variations	118	116	126	**33**
Type-II variations	47	61	41	**7**
Transfers	1	5	5	**1**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2014	2015	2016	2017
Submitted	10	24	13	**0**
Positive opinions	15	19	14	**4**
Negative opinions	0	0	0	**0**

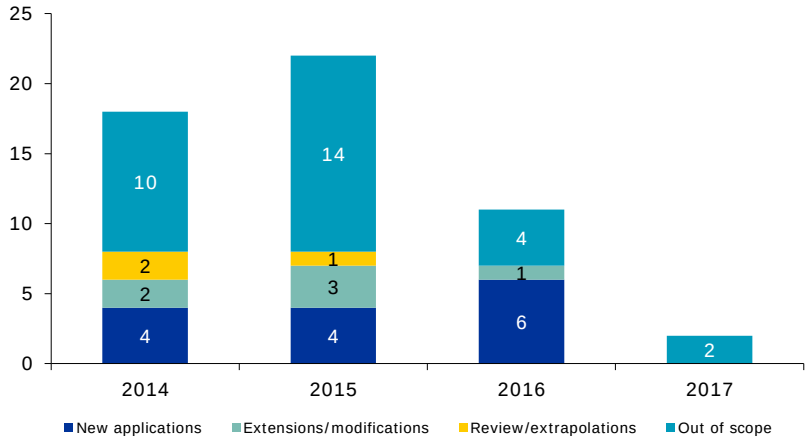
Establishment of MRLs for new substances[1] — applications	2014	2015	2016	2017
Submitted	4	4	6	**0**
Withdrawals	0	1	0	**0**
Positive opinions[2,3]	4	3 (1)	2	**0**
Negative opinions	0	0	0	**0**

Extensions / modifications of MRLs[4] — applications	2014	2015	2016	2017
Submitted	2	3	1	**0**
Withdrawals	0	0	1	**0**
Positive opinions[2]	8	2	3	**0**
Negative opinions	0	0	0	**0**

Review of opinions / extrapolations of MRLs[5] – requests from Commission or Member States	2014	2015	2016	2017
Submitted	2	1	0	**0**
Opinion[2]	2	3	0	**0**

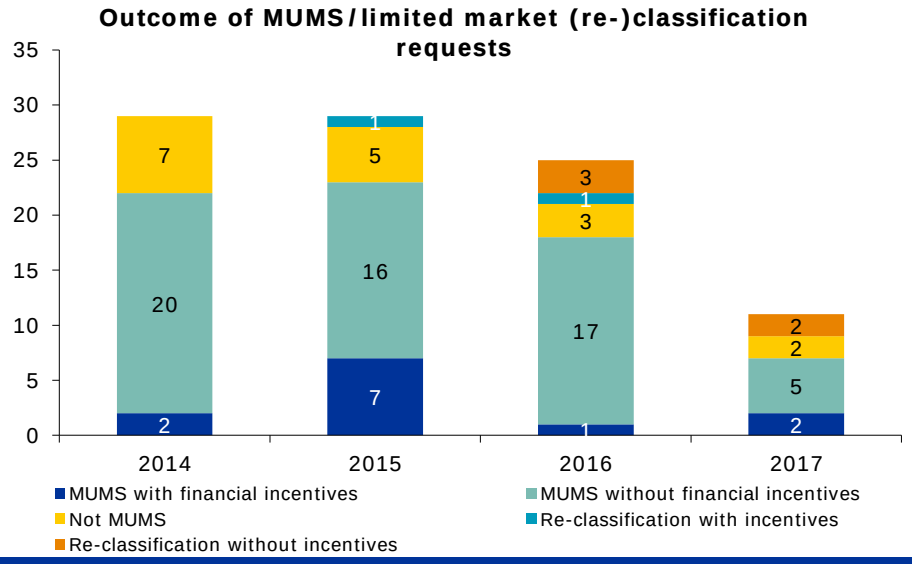
Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests	2014	2015	2016	2017
Submitted	10	14	4	**2**
Agreed	9	18	3	**1**
Not agreed	1	2	0	**0**
Scientific advice recommended	1	1	1	**1**

MRL-related submissions

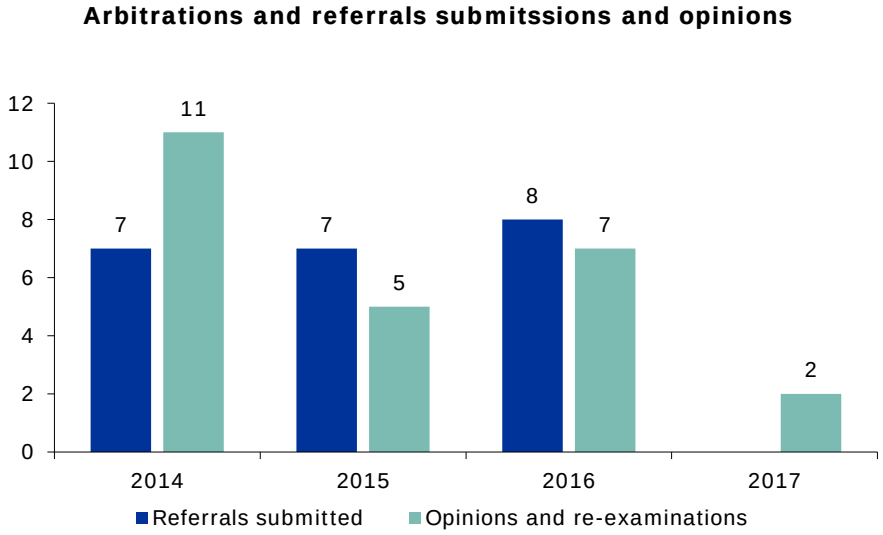


[1] Establishment of MRLs for new substances under article 3 of Regulation (EC) No 470/2009.
[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.
[3] Re-examinations of opinions are indicated in brackets.
[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 (re)classification requests — outcome	2014	2015	2016	2017
MUMS/limited market with financial incentives	2	6	1	**2**
MUMS/limited market without financial incentives	20	16	17	**5**
MUMS/limited market reclassification with financial incentives[6]	0	1	1	**0**
MUMS/limited market reclassification without financial incentives[6]	0	0	3	**2**
Not MUMS/limited market	7	5	3	**2**



Arbitrations and referrals	2014	2015	2016	2017
Arbitrations and referrals submitted	7	7	8	**0**
Opinions[7]	11 (1)	5	7	**2(1)**



[6] For re-classification the first year available is 2014.
[7] Re-examinations of opinions are in brackets.

CVMP opinions in 2017 on medicinal products for veterinary use

Positive opinions

Product • Invented name • INN/Common name	**Marketing authorisation holder**	**Target species**	**Regulatory information** • Procedure number • Opinion date
• Credelio • Lotilaner	• Elanco Europe Ltd	• Dog	• EMEA/V/C/004247/0000 • 16/02/2017
• CYTOPOINT • Lokivetmab	• Zoetis Belgium SA	• Dog	• EMEA/V/C/003939/0000 • 16/02/2017
• Zulvac BTV Ovis • Bluetongue vaccine (inactivated) (multistrain: 1-2 strains out of a set of 3)	• Zoetis Belgium SA	• Sheep	• EMEA/V/C/004185/0000 • 16/02/2017
• Ingelvac PCV FLEX • Porcine circovirus vaccine (inactivated)	• Boehringer Ingelheim Vetmedica GmbH	• Pig	• EMEA/V/C/004645/0000 • 16/03/2017
• RESPIPORC FLUpan H1N1 • Swine influenza vaccine (inactivated)	• IDT Biologika GmbH	• Pig	• EMEA/V/C/003993/0000 • 16/03/2017
• Zeleris • Florfenicol/meloxicam	• CEVA Santé Animale	• Cattle	• EMEA/V/C/004099/0000 • 16/03/2017

CVMP opinions in 2016 on establishment of MRLs

Positive opinions

Product • Substance	Target species	Regulatory information • Procedure number • Opinion date

Guidelines and working documents in 2017

CVMP quality

Reference number	Document title	Status
EMA/CHMP/CVMP/QWP/BWP/428135/2016	Draft Concept paper on the need for Revision of Note for guidance on quality of water for pharmaceutical use (H+V)	Adopted for consultation January 2017 (End of consultation 6 June 2017)
EMA/CHMP/CVMP/QWP/826771/2016	Corrigendum to Reflection paper on the Requirements for selection and justification of starting materials for the manufacture of chemical active substances	Adopted January 2017

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/377245/2016	Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products	Adopted for consultation February 2017 (End of consultation 31 August 2017)

CVMP efficacy

Reference number	Document title	Status
EMA/CVMP/344/1999-Rev.2	Guideline on the conduct of efficacy studies for intramammary products for use in cattle	Adopted January 2017

CVMP pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/171122/2016	Revised recommendation for the basic surveillance of Eudravigilance Veterinary (EVVet) data for centrally authorised products (CAPs)	Adopted for consultation February 2017 (End of consultation 31 August 2017)

CVMP antimicrobials

Reference number	Document title	Status

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/592652/2014	CVMP Risk Management Strategy - Managing the risk of the potential presence of replication competent endogenous retrovirus RD114 in starting materials and final products of feline and canine vaccines	Adopted February 2017

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/103555/2015	Guideline on assessing the toxicological risk to human health and groundwater communities from veterinary pharmaceuticals in groundwater	Adopted for consultation February 2017 (End of consultation 31 August 2017)
EMA/CVMP/ERA/689041/2015	Guideline on the plant testing strategy for veterinary medicinal products	Adopted March 2017

CVMP novel therapies

Reference number	Document title	Status

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

Reference number	Document title	Status

General

Reference number	Document title	Status
EMA/CVMP/757903/2016	Question and answer on the information contained within section 5.1 of the SPC on pharmacodynamic properties for pharmaceutical products	Adopted February 2017