13 February 2017
EMA/43619/2017
Veterinary Medicines Division

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

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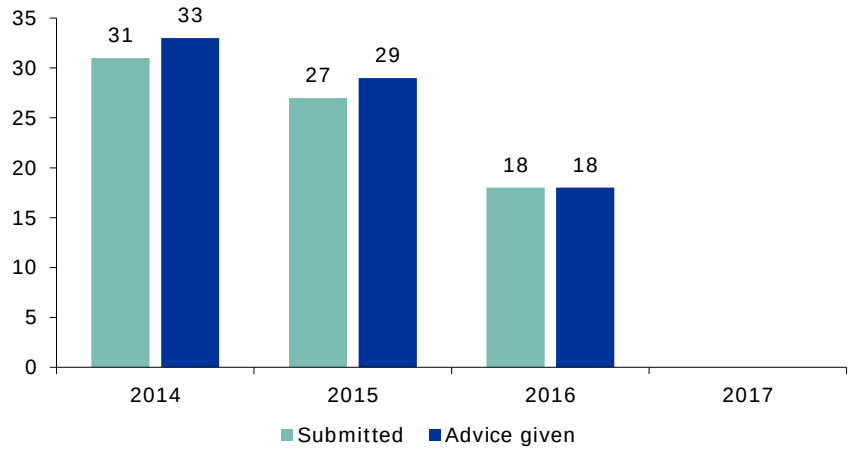
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

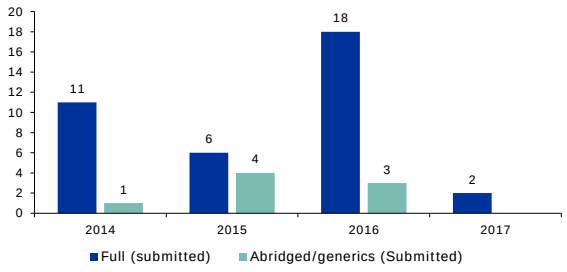
Scientific advice requests	2014	2015	2016	2017
Submitted and validated	31	27	18	**0**
Advice given	33	29	18	**0**

Scientific advice requests submitted and advice given

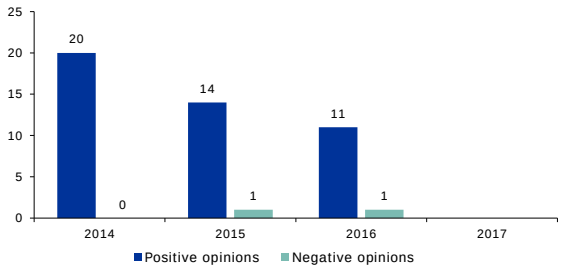


Initial evaluation of marketing authorisation applications	2014	2015	2016	2017
Full (submitted)	11	6	18	**2**
Abridged/generics (submitted)	1	4	3	**0**
Withdrawals	3	0	1	**0**
Positive opinions	20	14	11	**0**
Negative opinions	0	1	1	**0**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

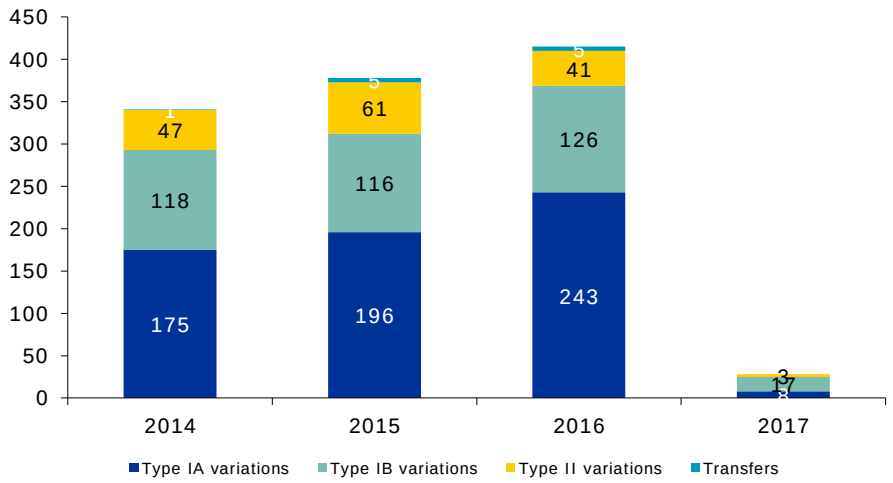


Marketing authorisations				
	2014	2015	2016	2017
Granted	19	17	7	**1**
Withdrawals	1	3	1	**0**
Refusal	0	1	0	**0**
Not renewed	0	0	1	**0**

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	2017
Type-IA variations	175	196	243	**8**
Type-IB variations	118	116	126	**17**
Type-II variations	47	61	41	**3**
Transfers	1	5	5	**0**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2014	2015	2016	2017
Submitted	10	24	13	**0**
Positive opinions	15	19	14	**2**
Negative opinions	0	0	0	**0**

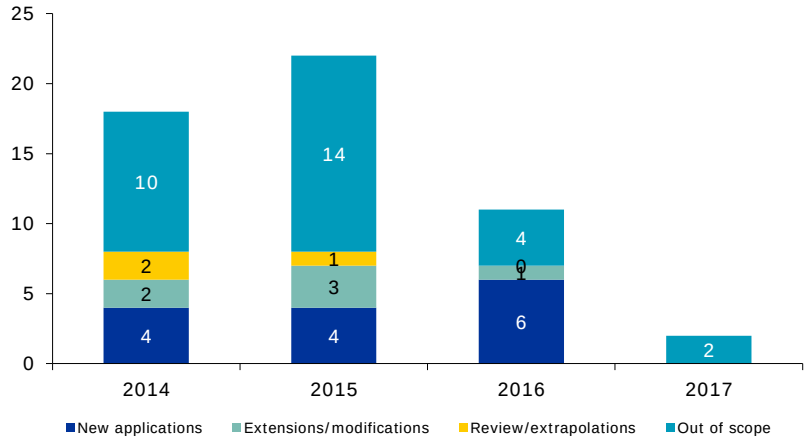
Establishment of MRLs for new substances[1] — applications				
	2014	2015	2016	2017
Submitted	4	4	6	**0**
Withdrawals	0	1	0	**0**
Positive opinions [2,3]	4	3 (1)	2	**0**
Negative opinions	0	0	0	**0**

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	**0**
Not agreed	1	2	0	**0**
Scientific advice recommended	1	1	1	**0**

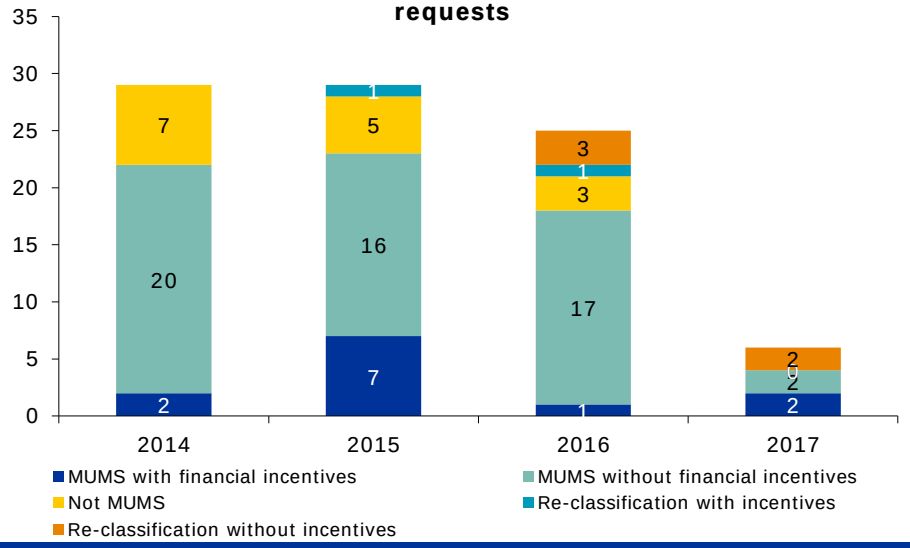
MRL-related submissions



[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.

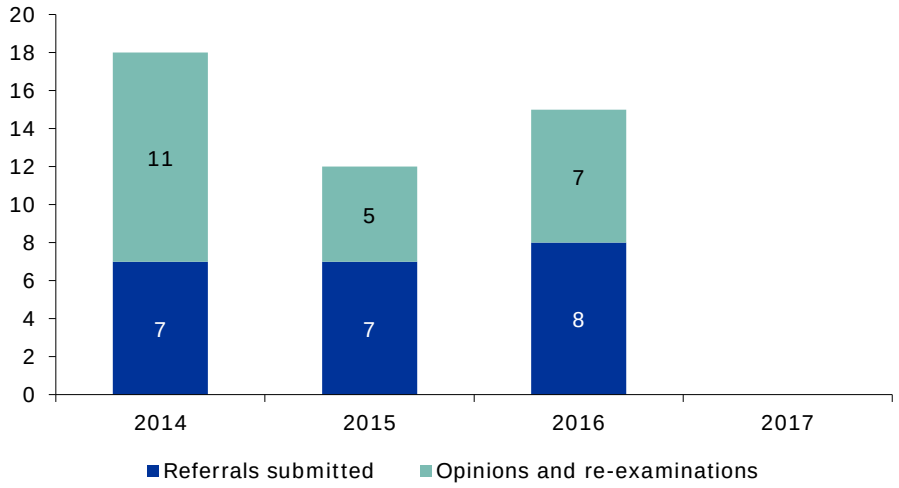
MUMS/limited market (re)classification requests — outcome	2014	2015	2016	2017
MUMS/limited market with financial incentives	2	6	1	**2**
MUMS/limited market without financial incentives	20	16	17	**2**
MUMS/limited market reclassification with financial incentives[6]	0	1	1	**0**
MUMS/limited market reclassification without financial incentives [6]	0	0	3	**2**
Not MUMS/limited market	7	5	3	**0**

Outcome of MUMS/limited market (re-)classification requests



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

Arbitrations and referrals submitted and opinions



[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

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 TBC)
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

CVMP efficacy

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

CVMP pharmacovigilance

Reference number	Document title	Status

CVMP antimicrobials

Reference number	Document title	Status

CVMP immunologicals

Reference number	Document title	Status

CVMP environmental risk assessment

Reference number	Document title	Status

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