25 April 2018
EMA/189006/2018
Veterinary Medicines Division

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

March 2018

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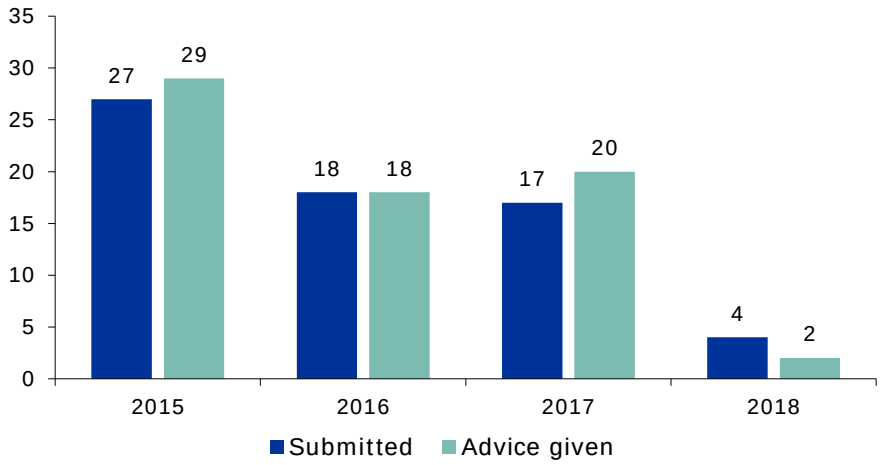
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

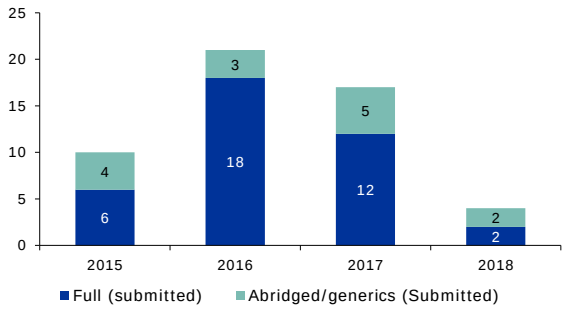
Scientific advice requests	2015	2016	2017	2018
Submitted and validated	27	18	**17**	**4**
Advice given	29	18	**20**	**2**

Scientific advice requests submitted and advice given

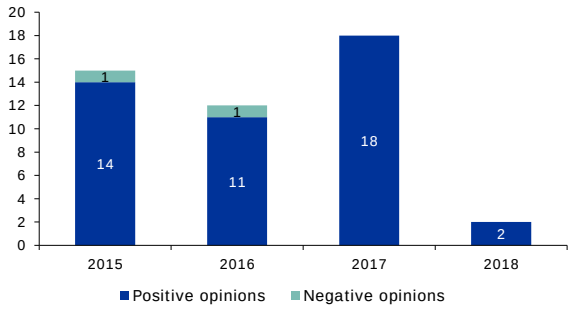


Initial evaluation of marketing authorisation applications	2015	2016	2017	2018
Full (submitted)	6	18	**12**	**2**
Abridged/generics (submitted)	4	3	**5**	**2**
Withdrawals	0	1	**1**	**1**
Positive opinions	14	11	**18**	**2**
Negative opinions	1	1	**0**	**0**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

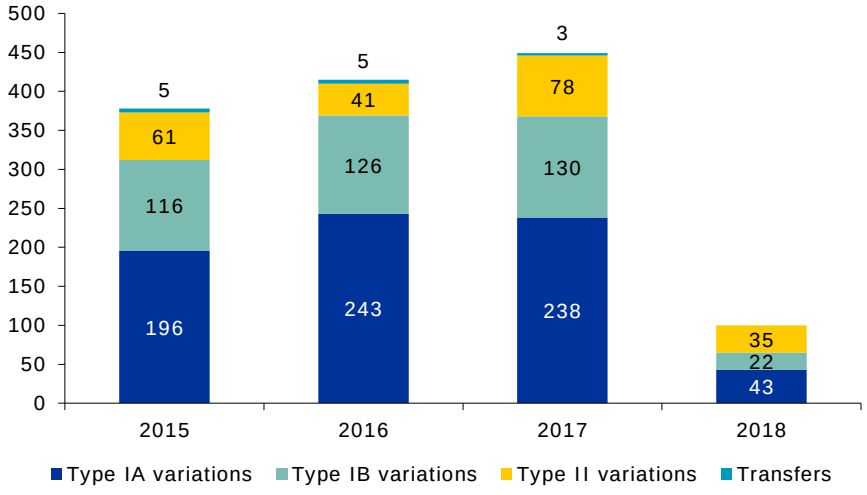


Marketing authorisations				
	2015	2016	2017	2018
Granted	17	7	**18**	**4**
Withdrawals	3	1	**0**	**0**
Refusal	1	0	**0**	**0**
Not renewed	0	1	**0**	**0**

Extensions — applications				
	2015	2016	2017	2018
Submitted	3	3	**5**	**0**
Withdrawals	0	0	**0**	**0**
Positive opinions	6	5	**2**	**1**
Negative opinions	1	0	**0**	**0**

Variations — applications submitted				
	2015	2016	2017	2018
Type-IA variations	196	243	**238**	**43**
Type-IB variations	116	126	**130**	**22**
Type-II variations	61	41	**78**	**35**
Transfers	5	5	**3**	**0**

Post-authorisation: submissions of variations and transfers



Renewals — applications				
	2015	2016	2017	2018
Submitted	24	13	**9**	**4**
Positive opinions	19	14	**10**	**4**
Negative opinions	0	0	**0**	**0**

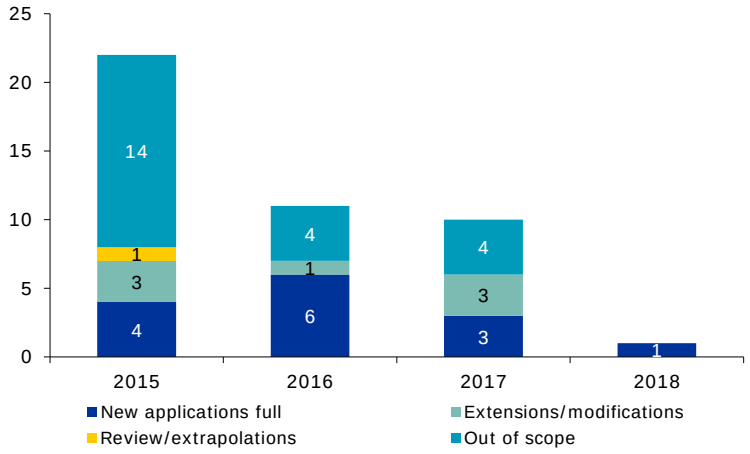
Establishment of MRLs for new substances[1] — applications				
	2015	2016	2017	2018
Submitted	4	6	**3**	**1**
Withdrawals	1	0	**2**	**1**
Positive opinions[2,3]	3 (1)	2	**4**	**0**
Negative opinions	0	0	**0**	**0**

Extensions / modifications of MRLs[4] — applications				
	2015	2016	2017	2018
Submitted	3	1	**3**	**0**
Withdrawals	0	1	**0**	**0**
Positive opinions[2]	2	3	**2**	**2**
Negative opinions	0	0	**0**	**0**

Review of opinions / extrapolations of MRLs[5] – requests from Commission or Member States				
	2015	2016	2017	2018
Submitted	1	0	**0**	**0**
Opinion[2]	3	0	**0**	**1**

Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2015	2016	2017	2018
Submitted	14	4	**4**	**0**
Agreed	18	3	**2**	**1**
Not agreed	2	0	**0**	**0**
Scientific advice recommended	1	1	**1**	**0**

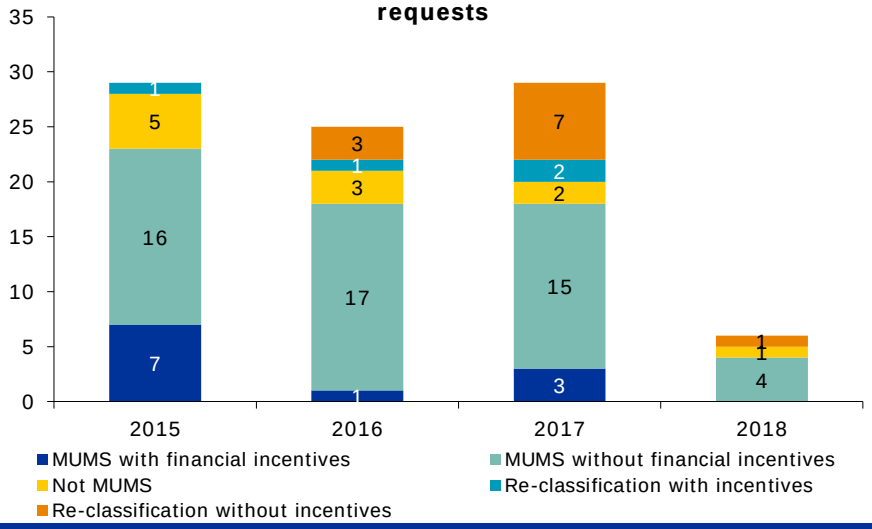
MRL-related submissions



[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.

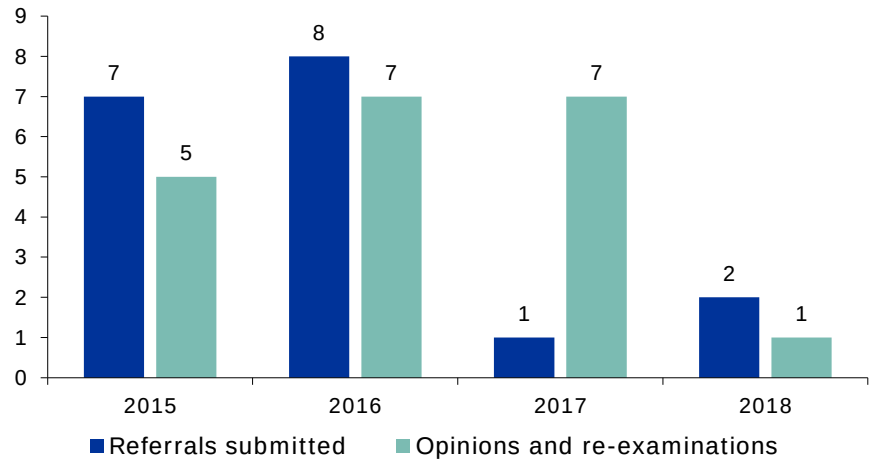
MUMS/limited market (re)classification requests — outcome	2015	2016	2017	2018
MUMS/limited market with financial incentives	7	1	**3**	**0**
MUMS/limited market without financial incentives	17	17	**15**	**4**
MUMS/limited market reclassification with financial incentives[6]	1	1	**2**	**0**
MUMS/limited market reclassification without financial incentives[6]	0	3	**7**	**1**
Not MUMS/limited market	5	3	**2**	**1**

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



Arbitrations and referrals	2015	2016	2017	2018
Arbitrations and referrals submitted	7	8	**1**	**2**
Opinions[7]	5	7	**7(1)**	**1(1)**

Arbitrations and referrals submissions and opinions



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

CVMP opinions in 2018 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
• Clevor • ropinirole	• Orion Corporation	• Dogs	• EMEA/V/C/004417/0000 • 15/02/2018
• Bravecto Plus • fluralaner/moxidectin	• Intervet International B.V.	• Cats	• EMEA/V/C/004440/0000 • 15/03/2018

CVMP opinions in 2018 on establishment of MRLs

Positive opinions

Product • Substance	Target species	Regulatory information • Procedure number • Opinion date
• Paromomycin	• Poultry eggs	• EMEA/V/MRL/003517/EXTN/0003 • 15/02/2018
• Isoflurane	• Porcine	• EMEA/V/MRL/003647/EXTN/0002 • 15/03/2018
• Diflubenzuron	• Salmonidae	• EMEA/V/MRL/003135/MODF/0003 • 15/03/2018

Arbitrations and referrals in 2018

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 34 of Directive 2001/82/EC (re-examination)	• 13/07/2016 • 05/10/2017 • 15/02/2018	• Girolan and its associated name Apralan • Apramycin sulfate
• Referral under Article 13 of Regulation (EC) No. 1234/2008	• 06/09/2017 • 15/02/2018	• Seresto and its associated name Foresto • Imidacloprid and flumethrin
• Referral under Article 35 of Directive 2001/82/EC	• 14/02/2018	• Veterinary medicinal products containing 50 mg closantel per ml presented as solutions for injection for subcutaneous use in sheep • Closantel
• Procedure under Article 30(3) of Regulation (EC) No. 726/2004	• 14/03/2018	• Veterinary medicinal products for food producing species containing diethanolamine as an excipient • Diethanolamine (excipient)

Guidelines and working documents in 2018

CVMP quality

Reference number	Document title	Status
EMA/CVMP/QWP/798401/2015	Guideline on Manufacture of the veterinary finished dosage form	Adopted for consultation February 2018 (End of consultation 22 October 2018)

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/779037/2017	Concept paper for the revision of the guideline on safety and residue data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted for consultation January 2018 (End of consultation 28 February 2018)

CVMP efficacy

No guidelines or working documents have yet been agreed in 2018.

CVMP pharmacovigilance

No guidelines or working documents have yet been agreed in 2018.

CVMP antimicrobials

No guidelines or working documents have yet been agreed in 2018.

CVMP immunologicals

No guidelines or working documents have yet been agreed in 2018.

CVMP environmental risk assessment

Reference number	Document title	Status
EMEA/CVMP/ERA/172074/2008 Rev. 6	Questions and Answers on the implementation of the CVMP guideline on environmental impact assessment for veterinary medicinal products in support of the VICH GL6 (Phase I) and GL38 (Phase II)	Adopted January 2018

CVMP novel therapies

No guidelines or working documents have yet been agreed in 2018.

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

No guidelines or working documents have yet been agreed in 2018.

General

Reference number	Document title	Status
EMA/CVMP/VICH/517152/2013	VICH GL57: Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species	Adopted for consultation January 2018 (end of consultation 15 June 2018)