4 November 2019
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Veterinary Medicines Division

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

August-September 2019

This report, which is updated every month, provides 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 to provide ongoing factual information. Commentaries and analysis are provided in the Agency's annual reports.

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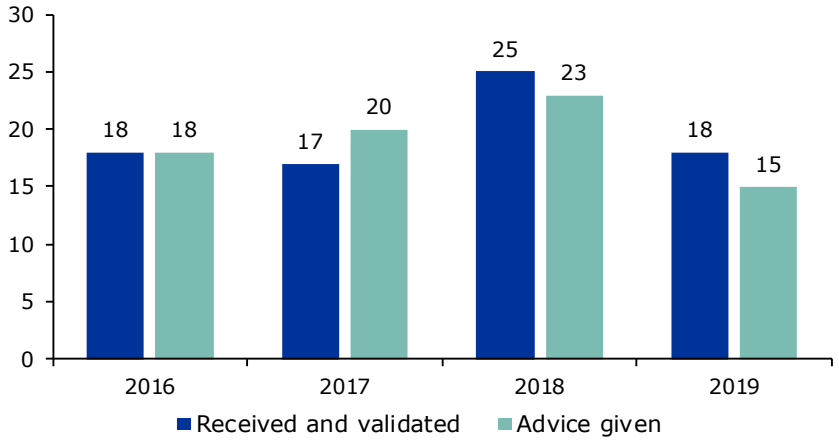
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

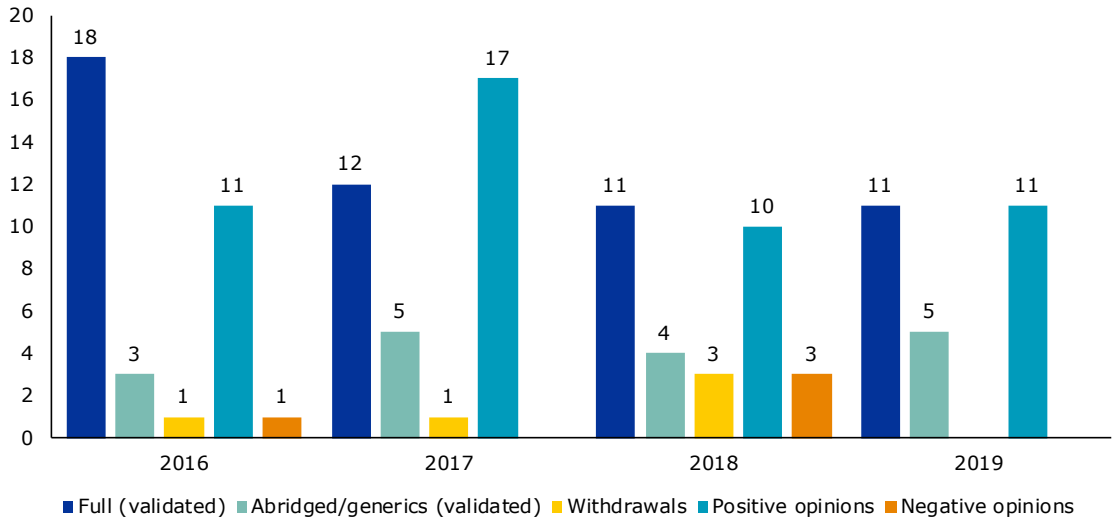
Scientific advice requests				
	2016	2017	2018	2019
Received and validated	18	17	25	**18**
Advice given	18	20	23	**15**

Scientific advice requests submitted and advice given



Initial evaluation of marketing authorisation – applications				
	2016	2017	2018	2019
Full (validated)	18	12	11	**11**
Abridged/generics (validated)	3	5	4	**5**
Withdrawals of applications	1	1	3	**0**
Positive opinions[1]	11	17(1)	10	**11(2)**
Negative opinions[1]	1	0	3	**(1)**

MMA submissions and outcomes



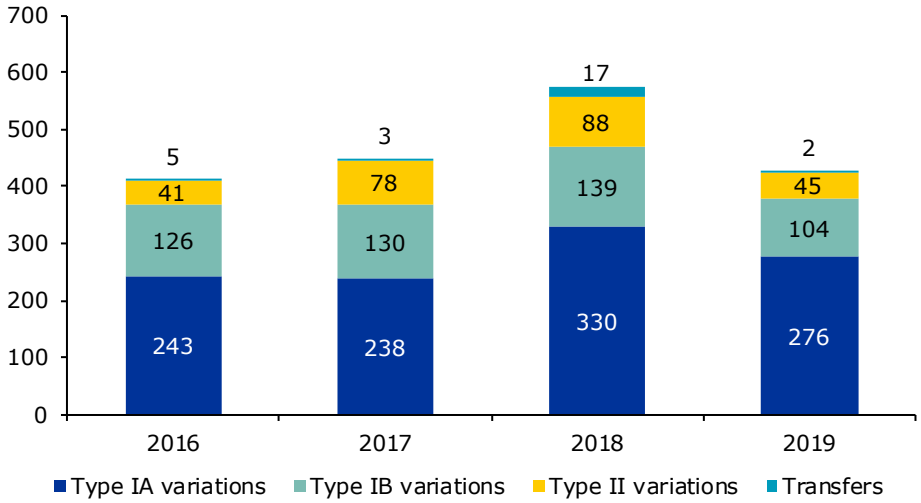
[1] Numbers for re-examinations or re-considerations (request by European Commission) of opinion are in brackets

Marketing authorisations[2]				
	2016	2017	2018	2019
Granted	7	18	9	**15**
Withdrawals	1	0	5	**3**
Refusals	0	0	1	**0**
Not renewed	1	0	2	**0**

Extensions — applications				
	2016	2017	2018	2019
Received and validated	3	5	1	**0**
Withdrawals	0	0	0	**0**
Positive opinions	5	2	5	**1**
Negative opinions	0	0	0	**0**

Variations — applications received				
	2016	2017	2018	2019
Type-IA variations	243	238	330	**276**
Type-IB variations	126	130	139	**104**
Type-II variations	41	78	88	**45**
Transfers	5	3	17	**2**

Post-authorisation: submissions of variations and transfers



Renewals — applications				
	2016	2017	2018	2019
Received and validated	13	9	24	**6**
Positive opinions	14	10	15	**17**
Negative opinions	0	0	0	**0**

[2] Marketing authorisations are granted by the European Commission

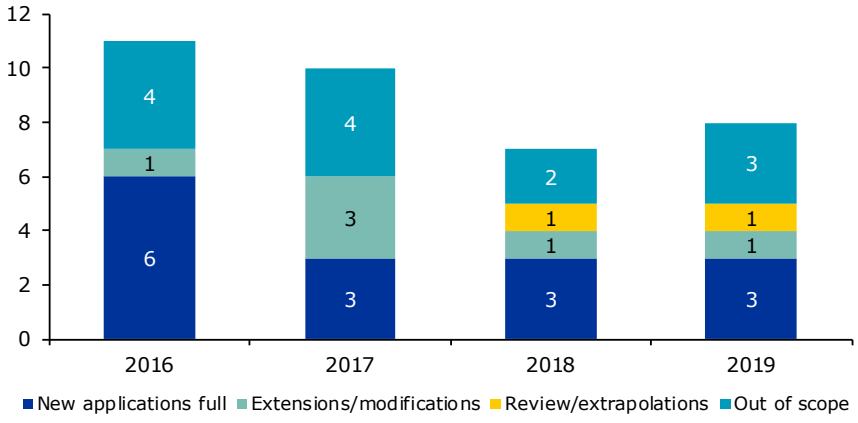
Establishment of MRLs for new substances[3] — applications				
	2016	2017	2018	2019
Received and validated	6	3	3	**3**
Withdrawals	0	2	2	**0**
Positive opinions[4,5]	2	4	1	**2**
Negative opinions	0	0	0	**0**

Extensions/modifications of MRLs[6] — applications				
	2016	2017	2018	2019
Received and validated	1	3	1	**1**
Withdrawals	1	0	0	**0**
Positive opinions[3]	3	2	2	**0**
Negative opinions	0	0	0	**0**

Review of opinions/extrapolations of MRLs[7]				
	2016	2017	2018	2019
Received and validated	0	0	1	**1**
Opinion[3]	0	0	1	**0**

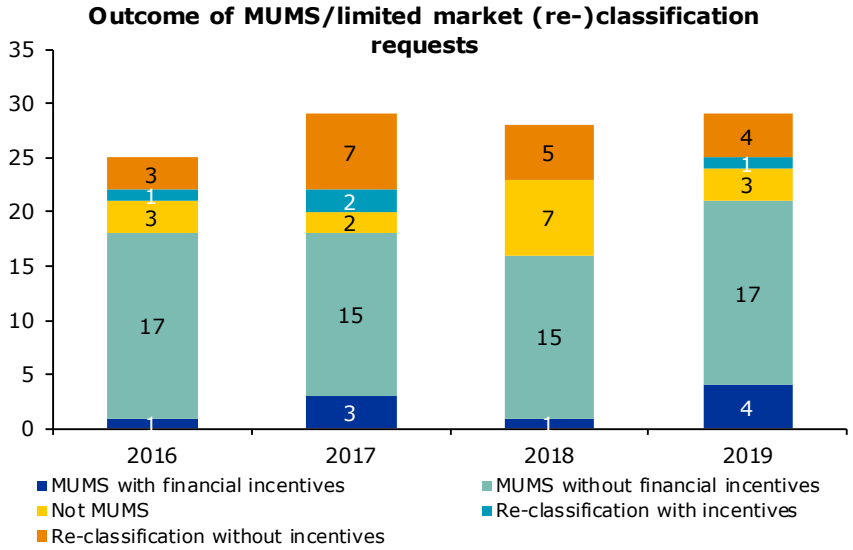
Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2016	2017	2018	2019
Received	4	4	2	**3**
Agreed	3	2	1	**1**
Not agreed	0	0	0	**0**
Scientific advice recommended	1	1	2	**0**

MRL-related submissions

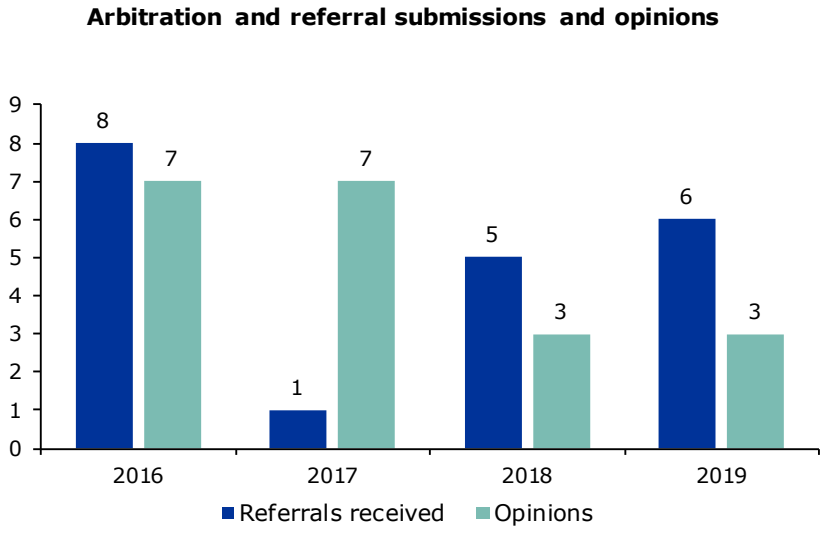


[3] Establishment of MRLs for new substances under article 3 of Regulation (EC) No 470/2009.
[4] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.
[5] Re-examinations of opinions are indicated in brackets.
[6] Extension or modification of MRLs under article 3 of Regulation (EC) No 470/2009.
[7] 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	2016	2017	2018	2019
MUMS/limited market with financial incentives	1	3	1	**4**
MUMS/limited market without financial incentives	17	15	15	**17**
MUMS/limited market reclassification with financial incentives	1	2	0	**1**
MUMS/limited market reclassification without financial incentives	3	7	5	**4**
Not MUMS/limited market	3	2	7	**3**



Arbitrations and referrals	2016	2017	2018	2019
Arbitrations and referrals received	8	1	5	**6**
Opinions[8]	7	7(1)	3(1)	**3**



[8] Re-examinations of opinions are in brackets.

CVMP opinions in 2019 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
• Chanhold • Selamectin	• Chanelle Pharmaceuticals Manufacturing Ltd.	• Cats and Dogs	• EMEA/V/C/004265/0000 • 21/02/2019
• Felisecto Plus • Selamectin/sarolaner	• Zoetis Belgium SA	• Cats	• EMEA/V/C/005093/0000 • 21/02/2019
• Forceris • Toltrazuril/iron (as gleptoferron)	• Ceva Santé Animale	• Piglets	• EMEA/V/C/004329/0000 • 21/02/2019
• ReproCyc ParvoFLEX • Porcine parvovirosis vaccine (inactivated)	• Boehringer Ingelheim Vetmedica GmbH	• Pigs	• EMEA/V/C/004858/0000 • 21/02/2019
• HorStem • Equine umbilical cord mesenchymal stem cells	• EquiCord-Ymas S.L.	• Horses	• EMEA/V/C/004265/0000 • 21/02/2019 (re-examination)
• Afoxolaner MERIAL • Afoxolaner	• MERIAL	• Dogs	• EMEA/V/C/005126/0000 • 21/03/2019
• Baycox Iron • Toltrazuril/iron(III) ion	• Bayer Animal Health GmbH	• Piglets	• EMEA/V/C/004794/0000 • 21/03/2019
• EVICTO • Selamectin	• Virbac S.A.	• Cats and Dogs	• EMEA/V/C/004973/0000 • 22/05/2019
• NASYM • Bovine respiratory syncytial virus vaccine (live)	• Laboratorios Hipra S.A.	• Cattle	• EMEA/V/C/004897/0000 • 22/05/2019
• Simparica Trio • Sarolaner, moxidectin and pyrantel embonate	• Zoetis Belgium SA	• Dogs	• EMEA/V/C/004846/0000 • 18/07/2019
• Gumbohatch • Avian infectious bursal disease vaccine (live)	• Laboratorios Hipra S.A.	• Chickens	• EMEA/V/C/004967/0000 • 12/09/2019
• Nobivac Myxo-RHD PLUS • Myxomatosis and rabbit haemorrhagic viral disease vaccine (live recombinant)	• Intervet International B.V.	• Rabbits	• EMEA/V/C/004989/0000 • 12/09/2019

Negative opinions

Product • Invented name • INN/Common name	Applicant	Target species	Regulatory information • Procedure number • Opinion date
• None	• None	• None	• None

CVMP opinions in 2019 on establishment of MRLs

Positive opinions

Product • Substance	**Target species**	**Regulatory information** • Procedure number • Opinion date
• Ciclesonide	• Horses	• EMEA/V/MRL/005010/FULL/0001 • 21/02/2019
• Bambermycin	• Rabbits	• EMEA/V/MRL/004828/FULL/0001 • 16/04/2019

Arbitrations and referrals in 2019

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 35 of Directive 2001/82/EC	• 14/02/2018 • 21/02/2019	• Veterinary medicinal products containing 50 mg closantel per ml presented as solutions for injection for subcutaneous use in sheep • Closantel
• Referral under Article 35 of Directive 2001/82/EC	• 10/10/2018 • 18/07/2019	• Veterinary medicinal products containing paromomycin to be administered parenterally to pigs • Paromomycin
• Referral under Article 35 of Directive 2001/82/EC	• 10/10/2018 • 20/06/2019	• Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep • Tylosin
• Referral under Article 35 of Directive 2001/82/EC	• 23/01/2019	• Veterinary medicinal products containing tylosin base (as a single active substance) presented as solutions for injection for intramuscular use in pigs • Tylosin base
• Referral under Article 35 of Directive 2001/82/EC	• 20/02/2019	• Betamox LA 150mg/ml Suspension for Injection and its associated names, and generic products thereof • Amoxicillin
• Referral under Article 33(4) of Directive 2001/82/EC	• 17/07/2019	• Ketabel 100 mg/ml solution for injection and associated names • Ketamine
• Referral under Article 34 of Directive 2001/82/EC	• 17/07/2019	• Adjusol and its associated names • Sulfadiazine and Trimethoprim
• Referral under Article 35 of Directive 2001/82/EC	• 11/09/2019	• Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names and generic products thereof • Dinoprost tromethamine
• Referral under Article 34 of Directive 2001/82/EC	• 11/09/2019	• Ronaxan and its associated names • Doxycycline hyclate

Guidelines and working documents in 2019

CVMP Quality

Reference number	Document title	Status
Quality of medicines questions and answers: Part 1	Use of peptone in the manufacture of active substance	Adopted March 2019

CVMP novel therapies

Reference number	Document title	Status
EMA/CVMP/ADVENT/803494/2016 – Rev.1	Revised Questions and Answers on allogeneic stem cell-based products for veterinary use: Specific questions on extraneous agents	Adopted June 2019
EMA/CVMP/ADVENT/751229/2016 - Rev.1	Revised Questions and Answers on allogeneic stem cell-based products for veterinary use: specific questions on sterility	Adopted June 2019

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 March 2019
EMA/CVMP/VICH/467/2003	VICH GL36(R2) Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI	Adopted March 2019
EMA/CVMP/CHMP/682199/2017	Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals - Preliminary risk profiling for new antimicrobial veterinary medicinal products	Adopted June 2019
Veterinary Post-authorisation webpage	Update of the veterinary post-authorisation guidance on the EMA public website	Finalised June 2019

Reference number	Document title	Status
EMA/CVMP/461776/2017	CVMP Reflection paper on promoting the authorisation of alternatives to antimicrobials in the EU	Adopted for consultation October 2019 End of consultation 30 April 2020