9 December 2019
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Veterinary Medicines Division

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

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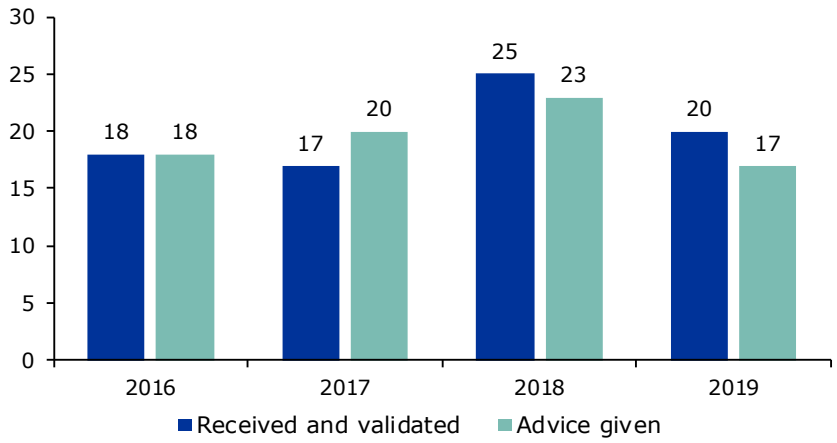
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

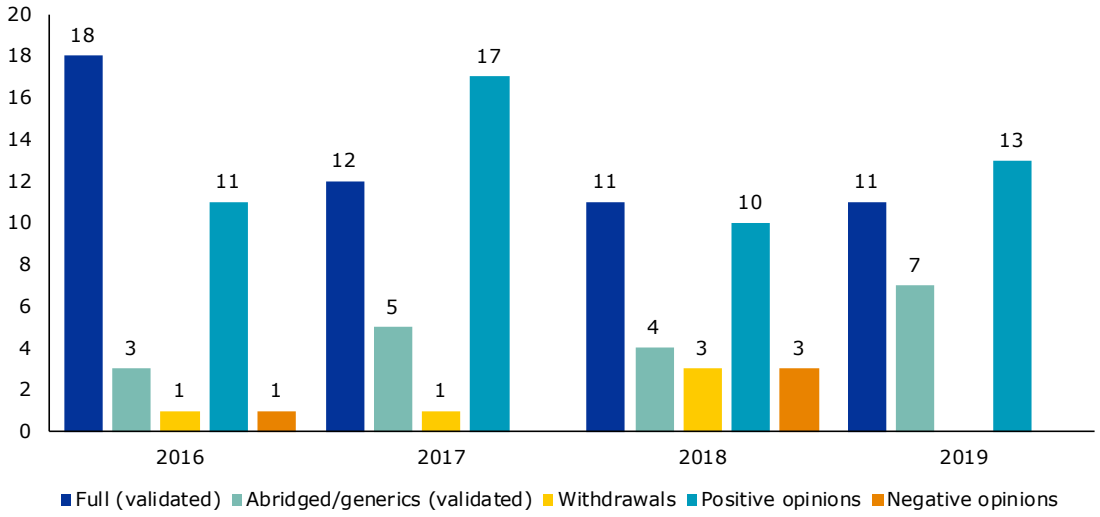
Scientific advice requests				
	2016	2017	2018	2019
Received and validated	18	17	25	**20**
Advice given	18	20	23	**17**

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	**7**
Withdrawals of applications	1	1	3	**0**
Positive opinions[1]	11	17(1)	10	**13(2)**
Negative opinions[1]	1	0	3	**(1)**

MMA submissions and outcomes



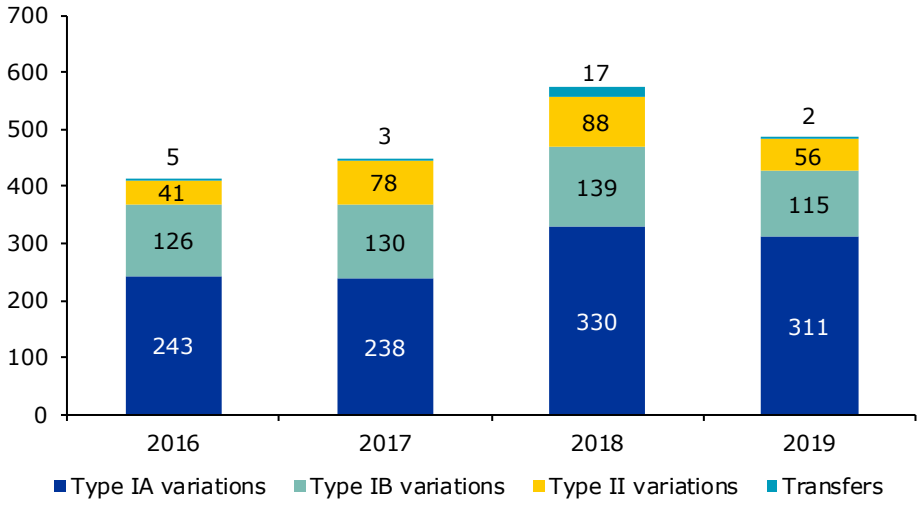
[1] Numbers for re-examinations or re-considerations (request by European Commission) of opinion are in brackets

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	**311**
Type-IB variations	126	130	139	**115**
Type-II variations	41	78	88	**56**
Transfers	5	3	17	**2**

Post-authorisation: submissions of variations and transfers



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

[2] Marketing authorisations are granted by the European Commission

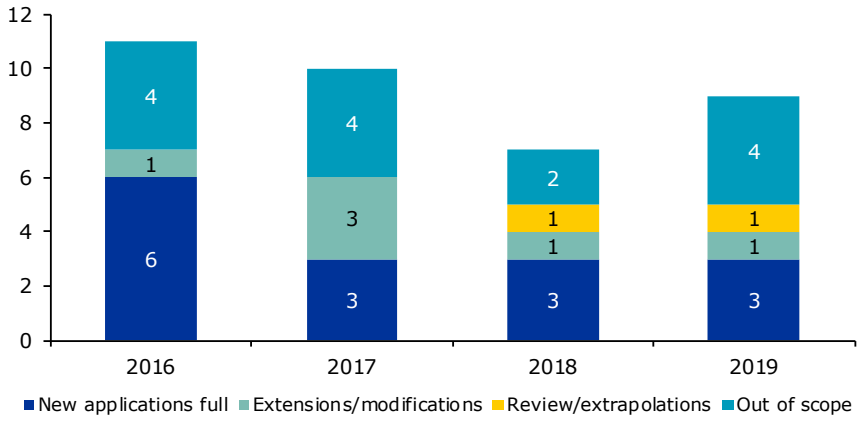
Establishment of MRLs for new substances[3] — applications				
	2016	2017	2018	2019
Received and validated	6	3	3	**3**
Withdrawals	0	2	2	**0**
Positive opinions[4,5]	2	4	1	**2**
Negative opinions	0	0	0	**0**

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	**1**

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

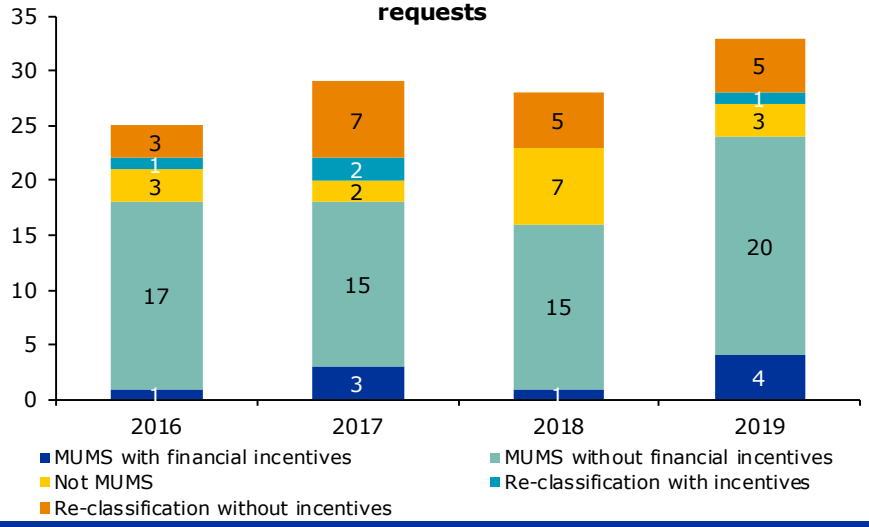
MRL-related submissions



[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.

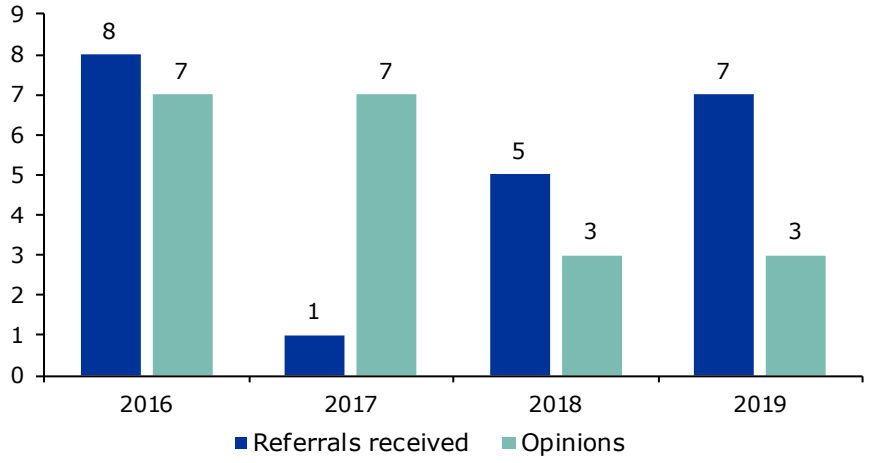
MUMS/limited market (re)classification requests — outcome	2016	2017	2018	2019
MUMS/limited market with financial incentives	1	3	1	**4**
MUMS/limited market without financial incentives	17	15	15	**20**
MUMS/limited market reclassification with financial incentives	1	2	0	**1**
MUMS/limited market reclassification without financial incentives	3	7	5	**5**
Not MUMS/limited market	3	2	7	**3**

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



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

Arbitration and referral submissions and opinions



[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

Product • Invented name • INN/Common name	Marketing authorisation holder	Target species	Regulatory information • Procedure number • Opinion date
• Mirataz • Mirtazapine	• Aniserve GmbH	• Cats	• EMEA/V/C/004733/0000 • 10/10/2019
• Neptra • Florfenicol/terbinafine hydrochloride/mometasone furoate	• Bayer Animal Health GmbH	• Dogs	• EMEA/V/C/004735/0000 • 10/10/2019

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
• Dicyclanil	• Sheep	• EMEA/V/MRL/003131/MODF/0003 • 10/10/2019

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

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 35 of Directive 2001/82/EC	• 09/10/2019	• Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof • Azaperone

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 in October 2019 End of consultation 30 April 2020