13 October 2017
EMA/516191/2017
Veterinary Medicines Division

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

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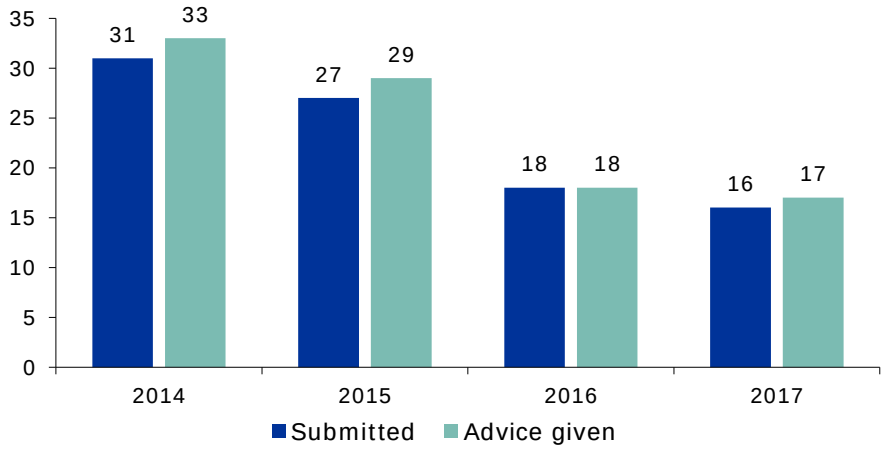
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

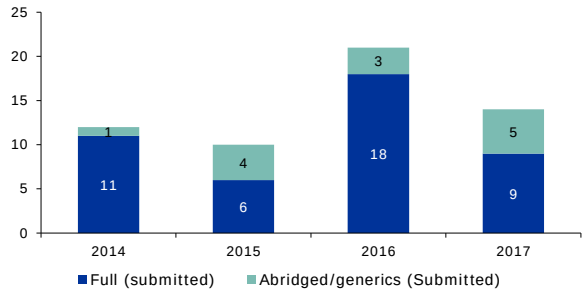
Scientific advice requests	2014	2015	2016	2017
Submitted and validated	31	27	18	**16**
Advice given	33	29	18	**17**

Scientific advice requests submitted and advice given

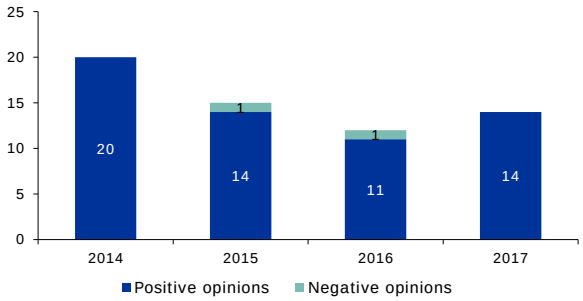


Initial evaluation of marketing authorisation applications	2014	2015	2016	2017
Full (submitted)	11	6	18	**9**
Abridged/generics (submitted)	1	4	3	**5**
Withdrawals	3	0	1	**1**
Positive opinions	20	14	11	**14**
Negative opinions	0	1	1	**0**

Pre-authorisation: submissions of MA applications by type



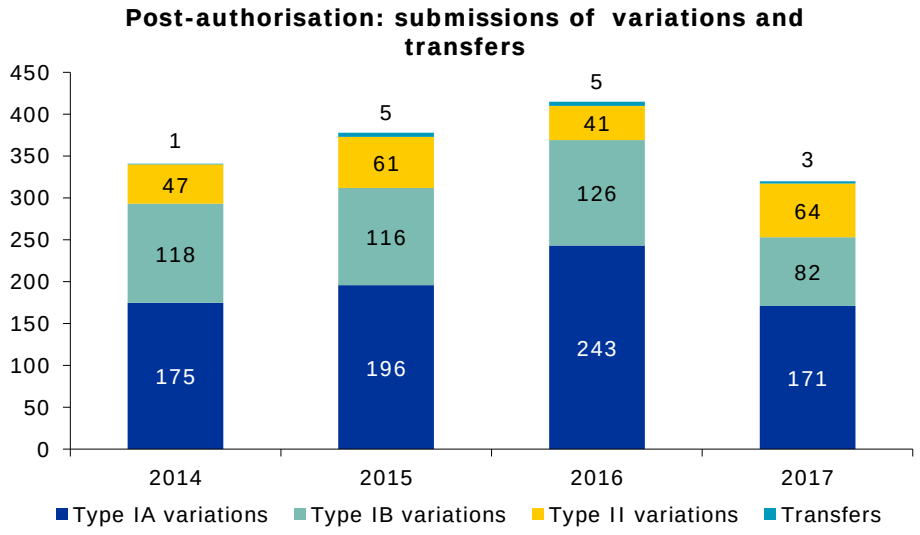
Pre-authorisation: outcome of the evaluation of MA applications



Marketing authorisations				
	2014	2015	2016	2017
Granted	19	17	7	**15**
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	**4**
Withdrawals	1	0	0	**0**
Positive opinions	2	6	5	**2**
Negative opinions	0	1	0	**0**

Variations — applications submitted				
	2014	2015	2016	2017
Type-IA variations	175	196	243	**171**
Type-IB variations	118	116	126	**82**
Type-II variations	47	61	41	**64**
Transfers	1	5	5	**3**



Renewals — applications				
	2014	2015	2016	2017
Submitted	10	24	13	**5**
Positive opinions	15	19	14	**6**
Negative opinions	0	0	0	**0**

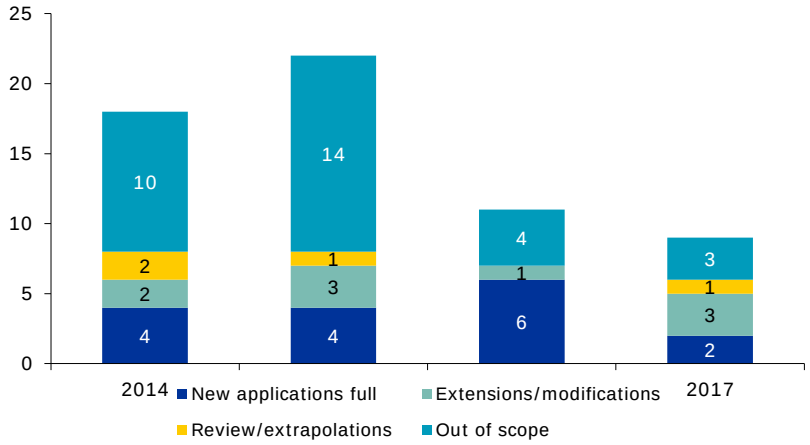
Establishment of MRLs for new substances[1] — applications				
	2014	2015	2016	2017
Submitted	4	4	6	**2**
Withdrawals	0	1	0	**2**
Positive opinions[2,3]	4	3 (1)	2	**2**
Negative opinions	0	0	0	**0**

Extensions / modifications of MRLs[4] — applications				
	2014	2015	2016	2017
Submitted	2	3	1	**3**
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	**1**
Opinion[2]	2	3	0	**0**

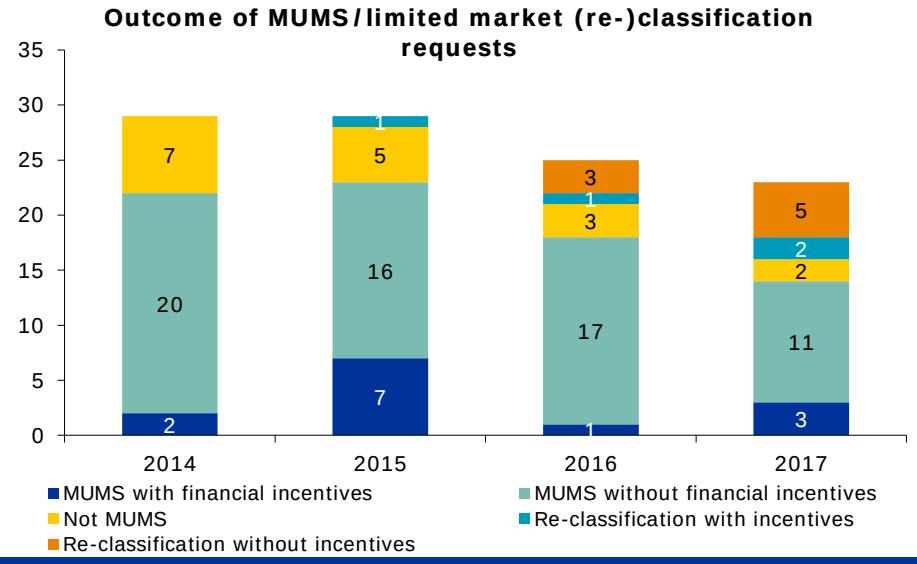
Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2014	2015	2016	2017
Submitted	10	14	4	**3**
Agreed	9	18	3	**2**
Not agreed	1	2	0	**0**
Scientific advice recommended	1	1	1	**1**

MRL-related submissions

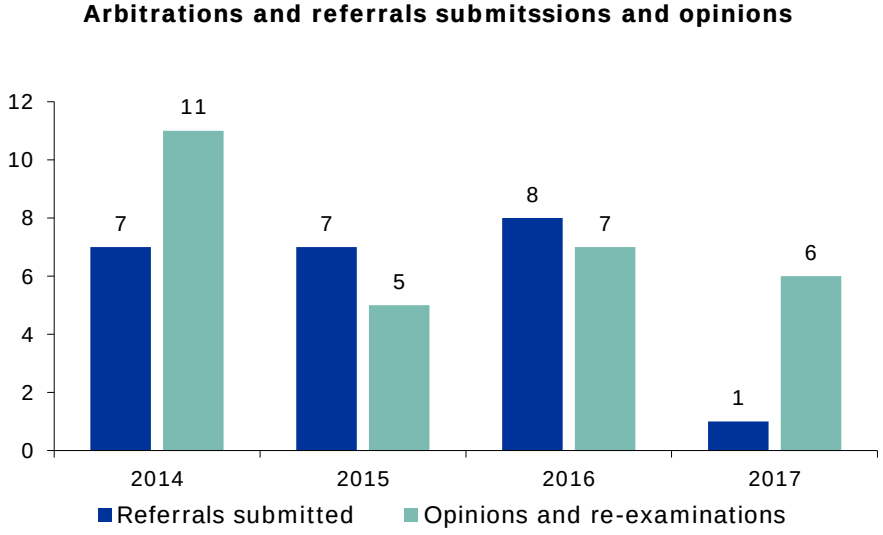


[1] Establishment of MRLs for new substances under article 3 of Regulation (EC) No 470/2009.
[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.
[3] Re-examinations of opinions are indicated in brackets.
[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	**3**
MUMS/limited market without financial incentives	20	16	17	**11**
MUMS/limited market reclassification with financial incentives[6]	0	1	1	**2**
MUMS/limited market reclassification without financial incentives[6]	0	0	3	**5**
Not MUMS/limited market	7	5	3	**2**



Arbitrations and referrals	2014	2015	2016	2017
Arbitrations and referrals submitted	7	7	8	**1**
Opinions[7]	11 (1)	5	7	**6(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
• **Prevomax** • Maropitant	• Le Vet Beheer B.V.	• Dogs, Cats	• EMEA/V/C/004331/0000 • 12/04/2017
• **Exzolt** • Fluralaner	• Intervet International B.V.	• Chickens	• EMEA/V/C/004344/0000 • 15/06/2017
• **Innovax-ND-IBD** • Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant)	• Intervet International B.V.	• Chickens	• EMEA/V/C/004422/0000 • 15/06/2017
• **Suvaxyn PRRS MLV** • Porcine respiratory and reproductive syndrome virus vaccine (live)	• Zoetis Belgium SA	• Pigs for fattening, Pigs for reproduction	• EMEA/V/C/004276/0000 • 15/06/2017
• **VEPURED** • *E. coli* verotoxoid vaccine (inactivated recombinant)	• Laboratorios Hipra, S.A.	• Pigs	• EMEA/V/C/004364/0000 • 15/06/2017

Product • Invented name • INN/Common name	Marketing authorisation holder	Target species	Regulatory information • Procedure number • Opinion date
• **Oxybee** • oxalic acid dihydrate	• Dany Bienenwohl	• Honey bees	• EMEA/V/C/004296 • 07/09/2017
• **Nobivac Leufel** • Feline leukaemia vaccine (inactivated)	• Virbac S.A.	• Cats	• EMEA/V/C/004778 • 07/09/2017
• **Bovilis Blue-8** • Bluetongue virus vaccine (inactivated) serotype 8	• Intervet Internaitonal B.V.	• Cattle, sheep	• EMEA/V/C/004776 • 07/09/2017

CVMP opinions in 2017 on establishment of MRLs

Positive opinions

Product • Substance	Target species	Regulatory information • Procedure number • Opinion date
• **Alarelin**	• All food producing species	• EMEA/V/MRL/04706/FULL/0001 • 12/04/2017
• **Bromelain**	• Porcine	• EMEA/V/MRL/004479/FULL/0001 • 11/05/2017

Arbitrations and referrals in 2017

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 34 of Directive 2001/82/EC	• 09/09/2015 • 12/04/2017	• Denagard 45% and associated names • Tiamulin hydrogen fumarate
• Referral under Article 35 of Directive 2001/82/EC	• 05/11/2015 • 11/05/2017	• All veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses • Moxidectin
• Referral under Article 35 of Directive 2001/82/EC (re-examination)	• 17/02/2016 • 08/12/2016 • 16/03/2017	• All veterinary medicinal products containing zinc oxide to be administered orally to food producing species • Zinc oxide
• Referral under Article 35 of Directive 2001/82/EC	• 18/05/2016 • 16/03/2017	• Veterinary medicinal products containing methylprednisolone hydrogen succinate presented as solutions for injection for intramuscular use in cattle • Methylprednisolone hydrogen succinate
• Referral under Article 35 of Directive 2001/82/EC	• 13/07/2016 • 16/03/2017	• Veterinary medicinal products containing tylosin to be administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma spp* • Tylosin
• Referral under Article 34 of Directive 2001/82/EC	• 13/07/2016	• Girolan and its associated name Apralan • Apramycin sulfate
• Referral under Article 34 of Directive 2001/82/EC	• 13/07/2016 • 13/07/2017	• Lincocin and associated names • Lincomycin
• Referral under Article 35 of Directive 2001/82/EC	• 07/09/2016 • 13/07/2017	• Zanil and associated names, and generic products thereof • Oxyclozanide
• Referral under Article 13 of Regulation (EC) No. 1234/2008	• 06/09/2017 •	• Seresto and its associated name Foresto • Imidacloprid and flumethrin

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
EMA/CHMP/CVMP/QWP/336031/2017	Reflection paper on the dissolution specification for generic solid oral immediate release products with systemic action	Adopted July 2017
EMA/CVMP/QWP/3629/2016	Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances	Adopted July 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
EMA/CVMP/EWP/573536/2013	Reflection paper on anthelmintic resistance	Adopted April 2017
EMA/CVMP/EWP/016/00-Rev.3	Revised guideline on the conduct of bioequivalence studies for veterinary medicinal products	Adopted for consultation April 2017 (End of consultation 31 October 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)
EMA/CVMP/PhVWP/303762/2012 - Rev. 1	Revised Questions and answers on serious non-fatal adverse events and reporting rules	Adopted April 2017
EMA/CVMP/PhVWP/357539/2015	Reflection paper on non-spontaneous adverse event reports (literature, internet and social media) for veterinary medicinal products	Adopted May 2017
EMA/CVMP/PhVWP/390033/2014 -Rev.1	Reflection paper on promotion of pharmacovigilance reporting	Adopted July 2017

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/AWP/237294/2017	Reflection paper on off-label use of antimicrobials in veterinary medicine in the European Union	Adopted for consultation July 2017 (End of consultation 19 January 2018)
EMA/CVMP/AWP/721118/2014	Reflection paper on use of aminoglycosides in animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation July 2017 (End of consultation 20 October 2017)

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
EMA/CVMP/IWP/123243/2006-Rev.3	Guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted April 2017

Reference number	Document title	Status
EMA/CVMP/IWP/105506/2007-Rev.1	Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)	Adopted for consultation September 2017 (End of consultation 31 March 2018)

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
EMA/CVMP/448211/2015	Authorisation of veterinary medicinal products containing (potential) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances	Adopted April 2017

CVMP novel therapies

Reference number	Document title	Status
EMA/CVMP/ADVENT/751229/2016	Questions and Answers on allogenic stem cell-based products for veterinary use: specific questions on sterility	Adopted June 2017
EMA/CVMP/ADVENT/803494/2016	Questions and Answers on allogenic stem cell-based products for veterinary use: Specific questions on extraneous agents	Adopted July 2017

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