29 January 2021
EMA/705858/2020
Veterinary Medicines Division

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

December 2020

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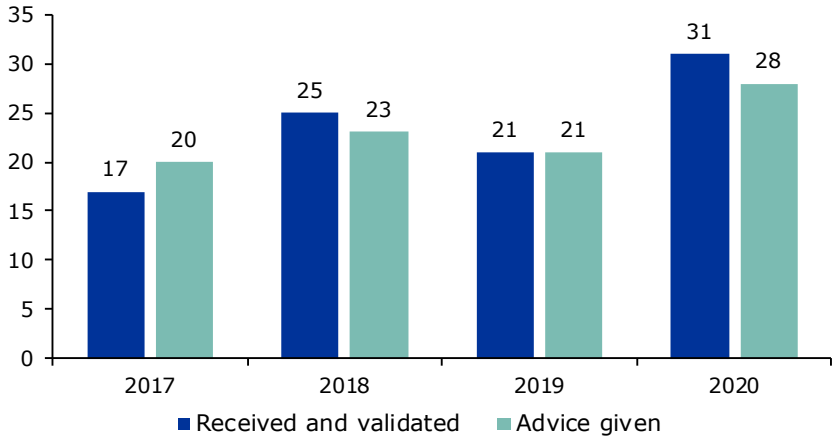
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

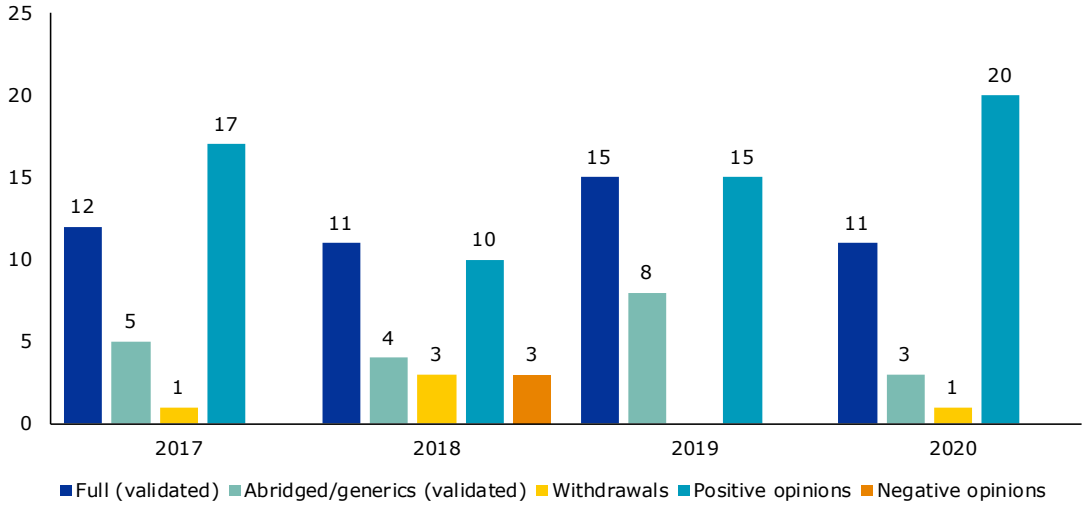
Scientific advice requests				
	2017	2018	2019	2020
Received and validated	17	25	21	**31**
Advice given	20	23	21	**28**

Scientific advice requests submitted and advice given



Initial evaluation of marketing authorisations – applications (MAA)				
	2017	2018	2019	2020
Full (validated)	12	11	15	**11**
Abridged/generics (validated)	5	4	8	**3**
Withdrawals of applications	1	3	0	**1**
Positive opinions[1]	17(1)	10	15(2)	**20**
Negative opinions[1]	0	3	(1)	**0**

MAA submissions and outcomes



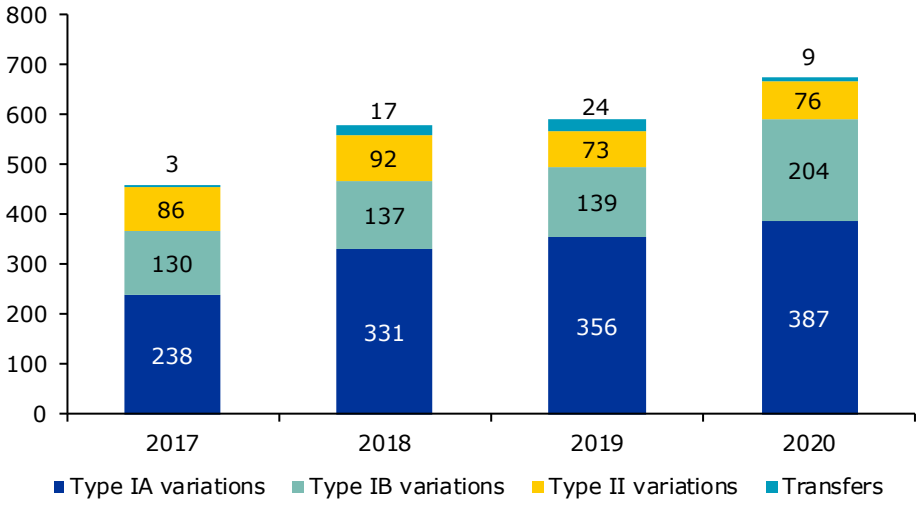
[1] Numbers for re-examinations or re-considerations (request by European Commission) of opinion are in brackets

Marketing authorisations[2]				
	2017	2018	2019	2020
Granted	18	9	19	**19**
Withdrawals	0	5	3	**4**
Refusals	0	1	0	**0**
Not renewed	0	2	0	**1**

Extensions — applications				
	2017	2018	2019	2020
Received and validated	5	1	2	**2**
Withdrawals	0	0	0	**0**
Positive opinions	2	5	1	**0**
Negative opinions	0	0	0	**0**

Variations — applications received				
	2017	2018	2019	2020
Type-IA variations	238	331	356	**387**
Type-IB variations	130	137	139	**204**
Type-II variations	78	92	73	**76**
Transfers	3	17	24	**9**

Post-authorisation: submissions of variations and transfers



Renewals — applications				
	2017	2018	2019	2020
Received and validated	9	24	11	**10**
Positive opinions	10	15	19	**14**
Negative opinions	0	0	0	**0**

[2] Marketing authorisations are granted by the European Commission

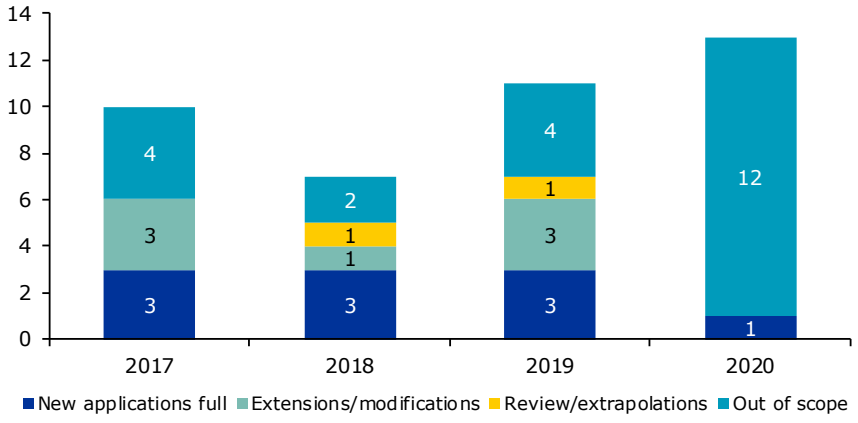
Establishment of MRLs for new substances[3] — applications				
	2017	2018	2019	2020
Received and validated	3	3	3	**1**
Withdrawals	2	2	0	**0**
Positive opinions[4,5]	4	1	2	**3**
Negative opinions	0	0	0	**0**

Extensions/modifications of MRLs[6] — applications				
	2017	2018	2019	2020
Received and validated	3	1	3	**0**
Withdrawals	0	0	0	**0**
Positive opinions	2	2	0	**2**
Negative opinions	0	0	0	**0**

Review of opinions/extrapolations of MRLs[7]				
	2017	2018	2019	2020
Received and validated	0	1	1	**0**
Opinion	0	1	1	**1**

Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests				
	2017	2018	2019	2020
Received	4	2	4	**12**
Agreed	2	1	3	**9**
Not agreed	0	0	1	**1**
Scientific advice recommended	1	2	0	**1**

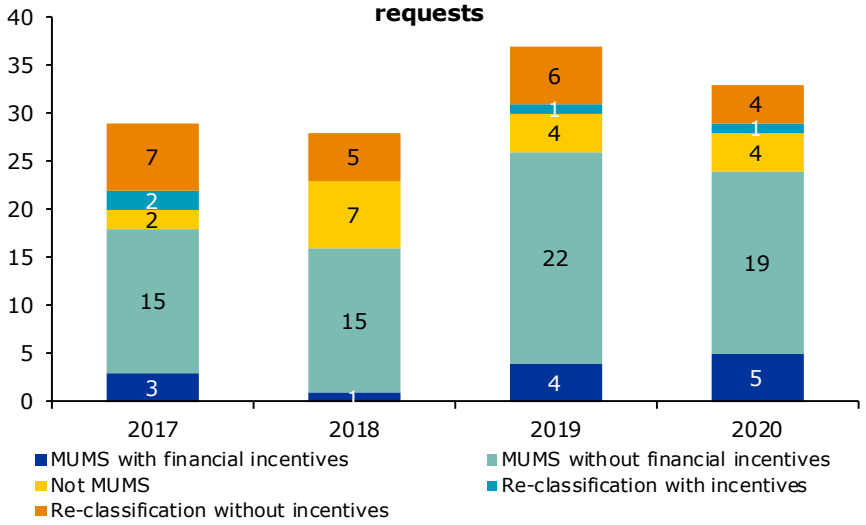
MRL-related submissions



[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.

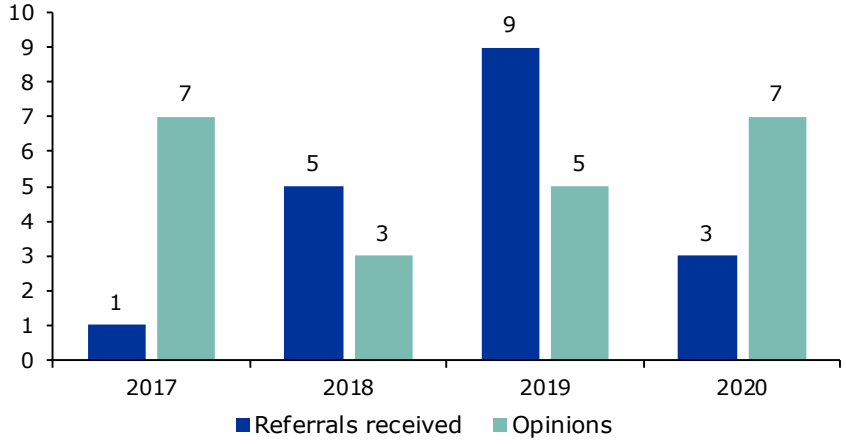
MUMS/limited market (re)classification requests — outcome	2017	2018	2019	2020
MUMS/limited market with financial incentives	3	1	4	**5**
MUMS/limited market without financial incentives	15	15	22	**19**
MUMS/limited market reclassification with financial incentives	2	0	1	**1**
MUMS/limited market reclassification without financial incentives	7	5	6	**4**
Not MUMS/limited market	2	7	4	**3**

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



Arbitrations and referrals	2017	2018	2019	2020
Arbitrations and referrals received	1	5	9	**3**
Opinions[8]	7(1)	3(1)	5	**7**

Arbitration and referral submissions and opinions



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

CVMP opinions in 2020 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
• Tulaven • Tulathromycin	• Ceva Santé Animale	• Cattle, Pigs, Sheep	• EMEA/V/C/005153/0000 • 20/02/2020
• Tulissin • Tulathromycin	• Virbac S.A.	• Cattle, Pigs, Sheep	• EMEA/V/C/005073/0000 • 20/02/2020
• Vectormune FP ILT + AE • Fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live)	• Ceva-Phylaxia Co. Ltd	• Chickens	• EMEA/V/C/005077/0000 • 20/02/2020
• Lydaxx • Tulathromycin	• Vetoquinol S.A.	• Cattle, Pigs, Sheep	• EMEA/V/C/005199/0000 • 18/03/2020
• Prevexxion RN • Marek's disease vaccine (live recombinant)	• Boehringer Ingelheim Vetmedica GmbH	• Chickens	• EMEA/V/C/005058/0000 • 20/05/2020
• Prevexxion RN+HVT+IBD • Infectious bursal disease and Marek's disease vaccine (live recombinant)	• Boehringer Ingelheim Vetmedica GmbH	• Chickens	• EMEA/V/C/005057/0000 • 20/05/2020
• Increxxa • Tulathromycin	• Elanco GmbH	• Cattle, Pigs, Sheep	• EMEA/V/C/005305/0000 • 16/07/2020
• Tulinovet • Tulathromycin	• VMD N.V.	• Cattle, Pigs, Sheep	• EMEA/V/C/005076/0000 • 16/07/2020
• Mhyosphere PCV ID • Porcine circovirus and Mycoplasma hyopneumoniae vaccine	• Laboratorios Hipra S.A.	• Pigs	• EMEA/V/C/005272/0000 • 16/07/2020

Product • Invented name • INN/Common name	Marketing authorisation holder	Target species	Regulatory information • Procedure number • Opinion date
• Innovax-ND-ILT • Marek's disease vaccine, Newcastle disease vaccine & infectious laryngotracheitis vaccine (live recombinant)	• Intervet International B.V.	• Chickens	• EMEA/V/C/005190/0000 • 16/07/2020
• Librela • Bedinvetmab	• Zoetis Belgium S.A.	• Dogs	• EMEA/V/C/005180/0000 • 09/09/2020
• Ovugel • Triptorelin acetate	• Vetoquinol S.A.	• Pigs	• EMEA/V/C/005219/0000 • 09/09/2020
• CircoMax Myco • Porcine circovirus vaccine (inactivated, recombinant) and Mycoplasma hyopneumoniae vaccine (inactivated)	• Zoetis Belgium S.A.	• Pigs	• EMEA/V/C/005184/0000 • 07/10/2020
• Enteroporc Coli AC • Neonatal piglet colibacillosis (recombinant, inactivated) and Clostridium perfringens vaccine (inactivated)	• IDT Biologika GmbH	• Pigs	• EMEA/V/C/005149/0000 • 07/10/2020
• Nobivac DP Plus • Canine distemper vaccine (live)and canine parvovirus vaccine (live, recombinant)	• Intervet International B.V.	• Dogs	• EMEA/V/C/005251/0000 • 07/10/2020
• Vectormune FP ILT • Fowlpox and avian infectious laryngotracheitis vaccine (live, recombinant)	• Ceva-Phylaxia Co. Ltd.	• Chickens	• EMEA/V/C/005482/0000 • 07/10/2020
• Rexxolide • Tulathromycin	• Dechra Regulatory B.V.	• Cattle, Pigs, Sheep	• EMEA/V/C/005384/0000 • 07/10/2020

Product • Invented name • INN/Common name	Marketing authorisation holder	Target species	Regulatory information • Procedure number • Opinion date
• Nexgard Combo • Esafoxolaner, Eprinomectin, Praziquantel	• Boehringer Ingelheim Vetmedica GmbH	• Cats	• EMEA/V/C/005094/0000 • 05/11/2020
• Enteroporc Coli • Neonatal piglet colibacillosis vaccine (recombinant, inactivated)	• IDT Biologika GmbH	• Pigs	• EMEA/V/C/005148/0000 • 05/11/2020
• Solensia • Frunevetmab	• Zoetis Belgium SA	• Cats	• EMEA/V/C/005179/0000 • 10/12/2020

Negative opinions

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

CVMP opinions in 2020 on establishment of MRLs

Positive opinions

Product • Substance	Target species	Regulatory information • Procedure number • Opinion date
• Bupivacaine	• Pigs	• EMA/V/MRL/005009/FULL/0001 • 20/02/2020
• Ketoprofen	• Horses, Pigs, Cattle	• EMA/V/MRL/003652/MODF/0003 • 18/03/2020
• Bupivacaine	• Cattle	• EMA/V/MRL/005009/FULL/0002 • 18/06/2020
• Lidocaine	• Pigs	• EMA/V/MRL/003549/EXTN/0002 • 16/07/2020
• Lidocaine	• Cattle	• EMA/V/MRL/003549/EXTN/0003 • 16/07/2020
• Imidacloprid	• Finfish	• EMA/V/MRL/004481/FULL/0002 • 09/09/2020

Arbitrations and referrals

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 35 of Directive 2001/82/EC	• 20/02/2019 • 16/07/2020	• Betamox LA 150 mg/ml Suspension for Injection and its associated names, and generic products thereof • Amoxicillin
• Referral under Article 34 of Directive 2001/82/EC	• 17/07/2019 • 10/12/2020	• Adjusol and its associated names • Sulfadiazine and trimethoprim
• Referral under Article 35 of Directive 2001/82/EC	• 11/09/2019 • 18/06/2020	• 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
• Referral under Article 35 of Directive 2001/82/EC	• 09/10/2019 • 16/07/2020	• Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof • Azaperone
• Referral under Article 35 of Directive 2001/82/EC	• 06/11/2019 • 09/09/2020	• Veterinary medicinal products containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use to be administered to pigs • Tiamulin hydrogen fumarate
• Procedure under Article 45 of Regulation (EC) No 726/2004	• 07/11/2019 • 20/05/2020	• Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs • Porcine respiratory and reproductive syndrome (PRRS) virus vaccine (live)
• Referral under Article 35 of Directive 2001/82/EC	• 19/02/2020 • 05/11/2020	• Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products • Albendazole
• Referral under Article 35 of Directive 2001/82/EC	• 15/07/2020	• Injectable veterinary medicinal products containing vitamin A for use in food producing species • Vitamin A (retinol and its esters)

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 35 of Directive 2001/82/EC	• 15/07/2020	• Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines • Porcine respiratory and reproductive syndrome virus vaccine (live)

Guidelines and working documents in 2020

CVMP Quality

Reference number	Document title	Status
EMA/CVMP/QWP/153641/2018	Reflection paper on risk management requirements for elemental impurities in veterinary medicinal products	Adopted January 2020
EMA/CVMP/QWP/631010/2017-Rev.2	Implementation of risk assessment requirements to control elemental impurities in veterinary medicinal Products	Adopted January 2020
EMA/CHMP/CVMP/QWP/496873/2018	Guideline on the quality of water for pharmaceutical use	Adopted June 2020

CVMP Safety

None.

CVMP Efficacy

None.

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/33617/2020	Veterinary Pharmacovigilance bulletin	Adopted March 2020
EMA/112926/2020	Pharmacovigilance regulatory recommendations for centrally authorised veterinary medicinal products during 2020	Report publication adopted April 2020, updated on a regular basis
EMA/CVMP/PhVWP/10418/2009-Rev.11	VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted May 2020
EMA/CVMP/PhVWP/288284/2007-Rev.12	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted May 2020
EMA/CVMP/PhVWP/145186/2013 – Rev. 4	Questions and answers on adverse event reporting	Adopted July 2020

CVMP Antimicrobials

Reference number	Document title	Status
EMA/CVMP/179874/2020	CVMP strategy on antimicrobials 2021-2025	Adopted for consultation June 2020 End of consultation 30 September 2020

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/669993/2019	Questions and Answers on management of extraneous agents in immunological veterinary medicinal products (IVMPs)	Adopted June 2020

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/52740/2012	Q&As in support of the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products	Finalised January 2020
EMA/CVMP/ERA/55512/2020	Concept paper for the development of a reflection paper on the environmental risk assessment for parasiticide veterinary medicinal products used in companion animals	Adopted for consultation April 2020 End of consultation 31 October 2020

CVMP Novel therapies

Reference number	Document title	Status
EMA/CVMP/ADVENT/791717/2016	Questions and Answers on Stem cell-based products for veterinary use: specific question on target animal safety to be addressed by ADVENT.	Adopted July 2020

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

None.

Regulation (EU) 2019/6 (Veterinary medicinal products)

Reference number	Document title	Status
EMA/CVMP/111028/2020	Scientific recommendations for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding good pharmacovigilance practice	Adopted May 2020
EMA/CVMP/123178/2019	Scientific recommendation for implementing measures under Article 77(6) of Regulation (EU) 2019/6 on veterinary medicinal products regarding the pharmacovigilance system master file	Adopted May 2020
EMA/CVMP/586518/2019	Advice on implementing measures under Article 57(4) of Regulation (EU) 2019/6 on veterinary medicinal products – Report on the format of the data to be collected on antimicrobial medicinal products used in animals	Adopted May 2020
EMA/567192/2019	Advice on implementing measures under Article 99(6) of Regulation (EU) 2019/6 on veterinary medicinal products – Good distribution practices (GDP) for veterinary medicinal products	Adopted June 2020
EMA/87754/2020	Advice on implementing measures under Article 95(8) of Regulation (EU) 2019/6 on veterinary medicinal products - Good distribution practices (GDP) for active substances used as starting materials in veterinary medicinal products	Adopted June 2020
EMA/CVMP/508559/2019	Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed	Adopted July 2020

Reference number	Document title	Status
EMA/CVMP/340959/2020	Concept paper on criteria for the application of Article 40(5) of Regulation (EU) 2019/6	Adopted for consultation July 2020 End of consultation 21 September 2020

Regulation (EU) 2019/6 EMA webpage: https://www.ema.europa.eu/en/veterinary-regulatory/overview/implementation-new-veterinary-medicines-regulation

Regulation (EU) 2019/6 EC webpage: https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/imp-regs-2019_en

General

Reference number	Document title	Status
EMA/CVMP/422/04 Rev. 2	Revised CVMP rules of procedure	Adopted April 2020
EMA/CVMP/VICH/677723/2016	VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use	Adopted December 2020