3 November 2021
EMA/555220/2021
Veterinary Medicines Division

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

August-September 2021

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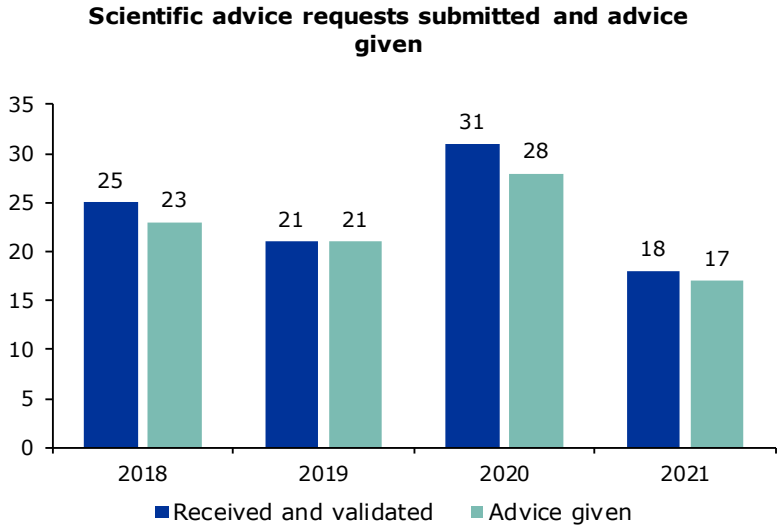
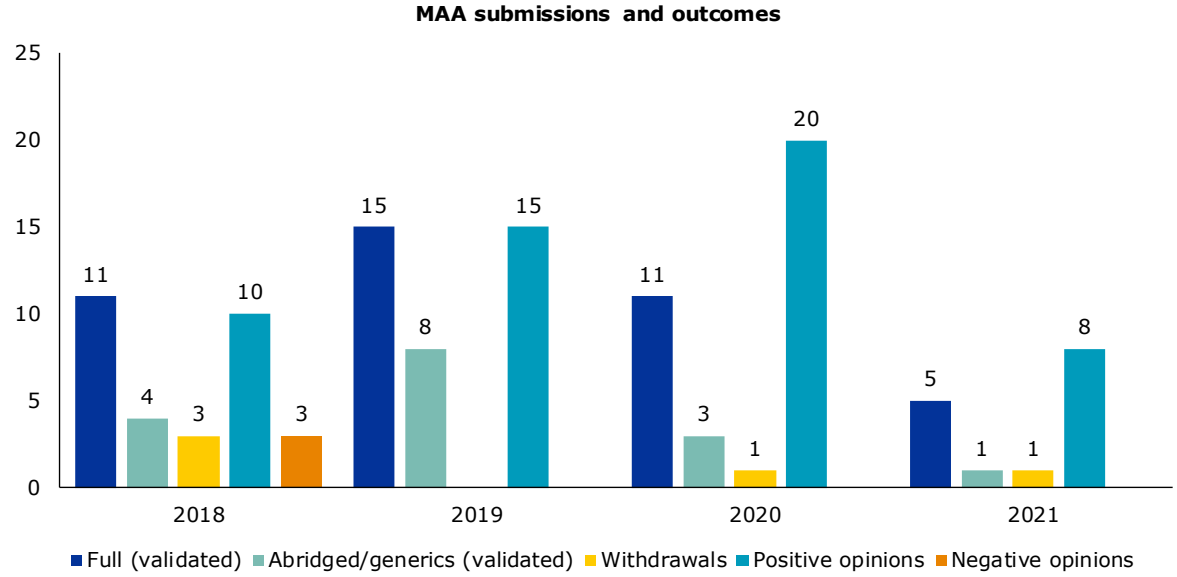
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

Scientific advice requests				
	2018	2019	2020	2021
Received and validated	25	21	31	**18**
Advice given	23	21	28	**17**



Initial evaluation of marketing authorisations – applications (MAA)				
	2018	2019	2020	2021
Full (validated)	11	15	11	**5**
Abridged/generics (validated)	4	8	3	**1**
Withdrawals of applications	3	0	1	**1**
Positive opinions[1]	10	15(2)	20	**8**
Negative opinions[1]	3	(1)	0	**-**



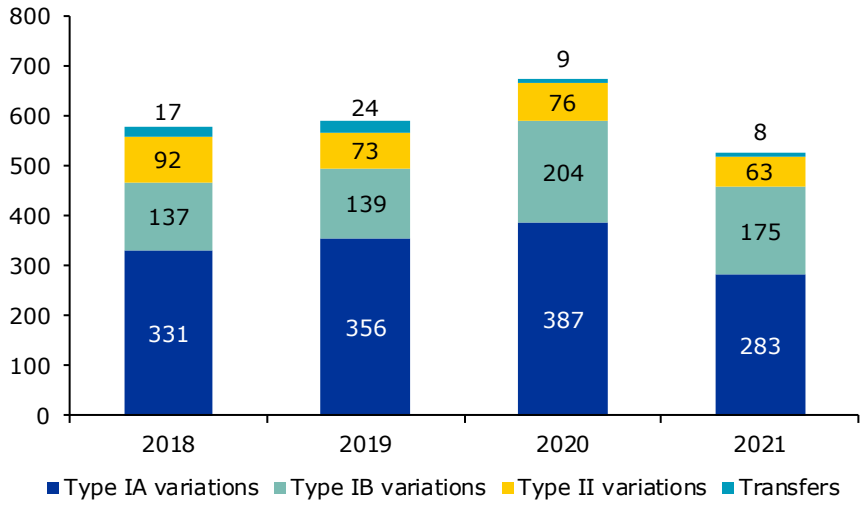
[1] Numbers for re-examinations or re-considerations (request by European Commission) of opinion are in brackets

Marketing authorisations[2]				
	2018	2019	2020	2021
Granted	9	19	19	**10**
Withdrawals	5	3	4	**3**
Refusals	1	0	0	**-**
Not renewed	2	0	3	**-**

Extensions — applications				
	2018	2019	2020	2021
Received and validated	1	2	2	**1**
Withdrawals	0	0	0	**1**
Positive opinions	5	1	0	**2**
Negative opinions	0	0	0	**-**

Variations — applications received				
	2018	2019	2020	2021
Type-IA variations	331	356	387	**283**
Type-IB variations	137	139	204	**175**
Type-II variations	92	73	76	**63**
Transfers	17	24	9	**8**

Post-authorisation: submissions of variations and transfers



Renewals — applications				
	2018	2019	2020	2021
Received and validated	24	11	10	**7**
Positive opinions	15	19	14	**6**
Negative opinions	0	0	0	**-**

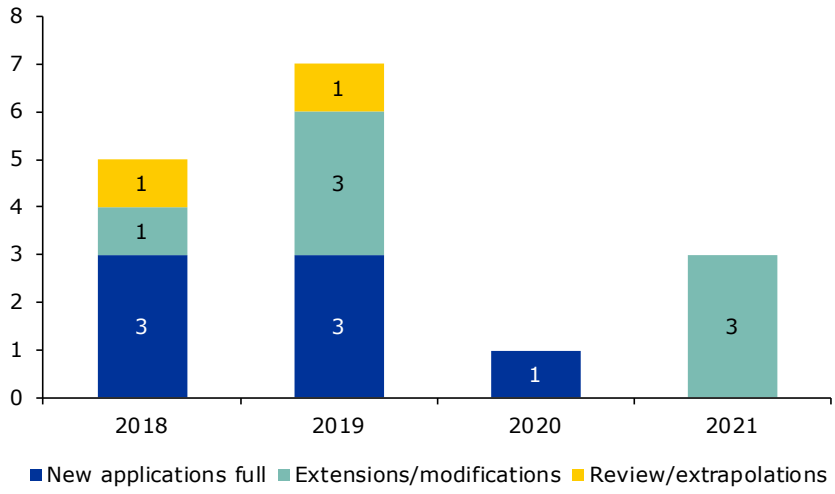
[2] Marketing authorisations are granted by the European Commission

Establishment of MRLs for new substances[3] — applications				
	2018	2019	2020	2021
Received and validated	3	3	1	-
Withdrawals	2	0	0	1
Positive opinions[4,5]	1	2	3	-
Negative opinions	0	0	0	-

Extensions/modifications of MRLs[6] — applications				
	2018	2019	2020	2021
Received and validated	1	3	0	3
Withdrawals	0	0	0	1
Positive opinions	2	0	2	1
Negative opinions	0	0	0	-

Review of opinions/extrapolations of MRLs[7]				
	2018	2019	2020	2021
Received and validated	1	1	0	-
Opinion	1	1	1	-

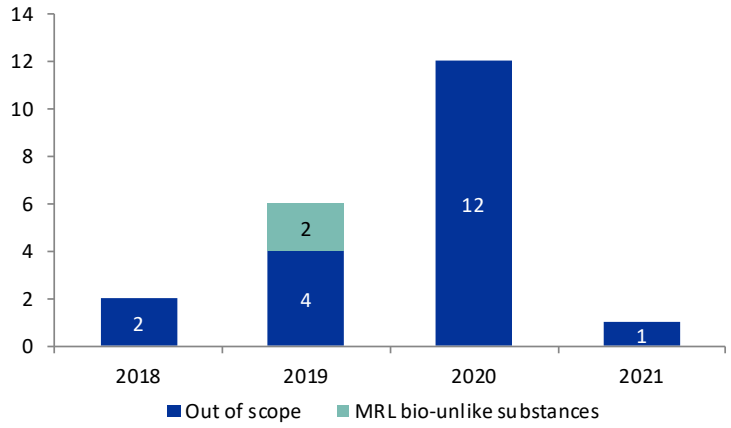
MRL submissions



[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.

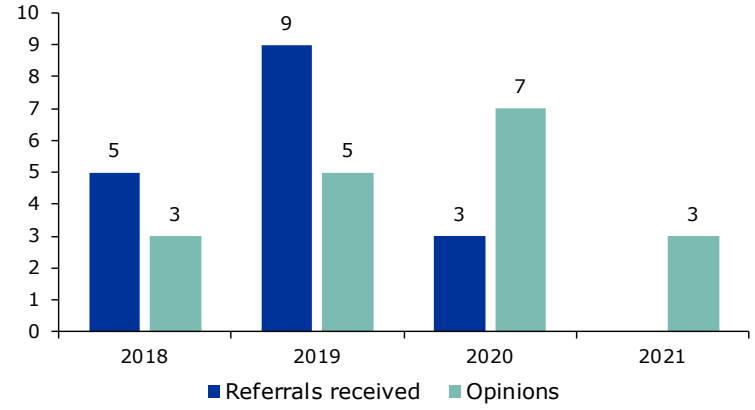
Other MRL-related submissions				
	2018	2019	2020	2021
Out of scope requests[8], of which				
Received	2	4	12	**1**
Agreed	1	3	9	**-**
Not agreed	0	1	1	**-**
Scientific advice recommended	2	0	1	**2**
Need for an MRL evaluation for 'chemical-unlike' biological substances[9], of which				
Received	-	2	-	**-**
MRL evaluation not necessary	-	-	1	**1**
MRL evaluation necessary	-	-	-	**-**

MRL-related submissions



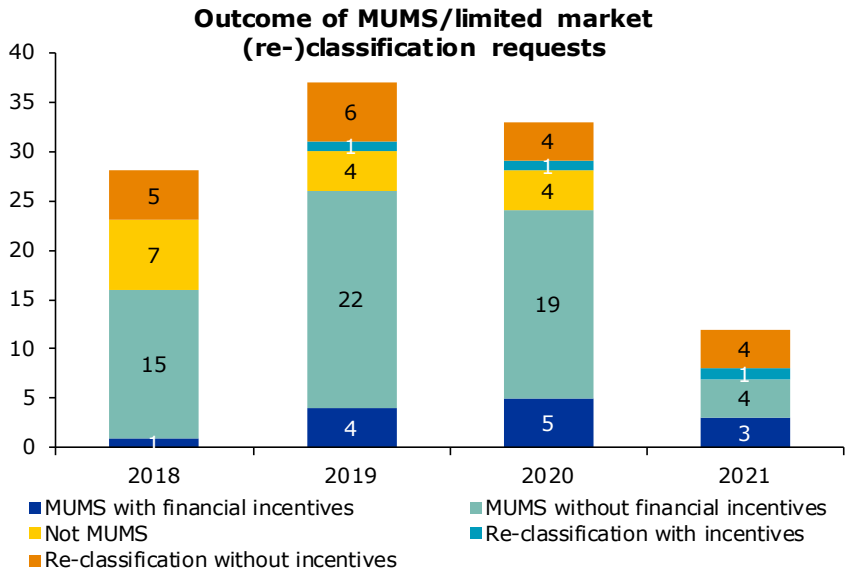
Arbitrations and referrals				
	2018	2019	2020	2021
Arbitrations and referrals received	5	9	3	**-**
Opinions[10]	3(1)	5	7	**3**

Arbitration and referral submissions and opinions



[8] Substances considered as not falling within the scope of Regulation (EC) No 470/2009
[9] According to Section I.6 of Annex I to Commission Regulation (EU) 2018/782
[10] Re-examinations of opinions are in brackets.

MUMS/limited market (re)classification requests — outcome				
	2018	2019	2020	2021
MUMS/limited market with financial incentives	1	4	**5**	**3**
MUMS/limited market without financial incentives	15	22	**19**	**4**
MUMS/limited market reclassification with financial incentives	0	1	**1**	**1**
MUMS/limited market reclassification without financial incentives	5	6	**4**	**4**
Not MUMS/limited market	7	4	**3**	**-**



CVMP opinions in 2021 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 Plus • Lotilaner/Milbemycin oxime	• Elanco GmbH	• Dogs	• EMEA/V/C/005325/0000 • 17/02/2021
• Daxocox • Enflicoxib	• Ecuphar NV	• Dogs	• EMEA/V/C/005354/0000 • 17/02/2021
• Ultifend ND IBD • Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant)	• Ceva-Phylaxia Veterinary	• Chickens	• EMEA/V/C/005347/0000 • 17/02/2021
• Bonqat • Pregabalin	• Orion Corporation	• Cats	• EMEA/V/C/005489/0000 • 12/05/2021
• Tessie • Tasipimidine	• Orion Corporation	• Dogs	• EMEA/V/C/005427/0000 • 17/06/2021
• Fatrovax RHD • Rabbit haemorrhagic disease vaccine (inactivated, recombinant)	• Fatro S.p.A	• Rabbits	• EMEA/V/C/005301/0000 • 17/06/2021
• Strangvac • *Streptococcus equi* vaccine (recombinant proteins)	• Intervacc AB	• Horses	• EMEA/V/C/005309/0000 • 17/06/2021
• Felpreva • Tigolaner-/ Emodepside-/ Praziquantel	• Vetoquinol SA	• Cats	• EMEA/V/C/005464/0000 • 09/09/2021

Negative opinions

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

CVMP opinions in 2021 on establishment of MRLs

Positive opinions

Product • Substance	Target species	Regulatory information • Procedure number • Opinion date
• Bambermycin	• Chickens	• EMEA/V/C/004828/EXTN/0002 • 15/07/2021

Arbitrations and referrals

Ongoing procedures

Type of procedure	Date • Clock start • CVMP opinion	Product • Product name • INN
• Referral under Article 34 of Directive 2001/82/EC	• 11/09/2019 • 17/06/2021	• Ronaxan and its associated names • Doxycycline hyclate
• Referral under Article 35 of Directive 2001/82/EC	• 15/07/2020 • 12/05/2021	• Injectable veterinary medicinal products containing vitamin A for use in food producing species • Vitamin A (retinol and its esters)
• Referral under Article 35 of Directive 2001/82/EC	• 15/07/2020 • 15/04/2021	• Modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines • Porcine respiratory and reproductive syndrome virus vaccine (live)

Guidelines and working documents in 2021

CVMP Quality

Reference number	Document title	Status
EMA/CVMP/QWP/798401/2015	Guideline on Manufacture of the Veterinary Finished Dosage Form	Adopted July 2021
EMA/CVMP/QWP/485008/2019	Overview of comments received on the guideline on Manufacture of the Veterinary Finished Dosage Form (EMA/CVMP/QWP/798401/2015)	Adopted July 2021

CVMP Safety

Reference number	Document title	Status
EMA/CVMP/345237/2020	Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/345236/2020	Safety and residue data requirements for the establishment of Maximum Residue Limits in minor species	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/SWP/265238/2021	Concept paper for the revision of residues guidelines to align with the definitions for withdrawal periods provided in Regulation (EU) 2019/6	Adopted June 2021 for consultation End of consultation: 31 July 2021
EMA/CVMP/SWP/207500/2021	Concept paper on the development of a guideline on determination of the need for an MRL evaluation for biological substances	Adopted July 2021 for consultation End of consultation 30 September 2021
EMA/CVMP/345237/2020	Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted July 2021

Reference number	Document title	Status
EMA/CVMP/148001/2021	Overview of comments received on 'Guideline on safety and residue data requirements for applications for nonimmunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 (EMA/CVMP/345237/2020)	Adopted September 2021

CVMP Efficacy

Reference number	Document title	Status
EMA/CVMP/52665/2020	Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/EWP/165592/2021	Concept paper for the revision of the guideline on the summary of product characteristics for anthelmintics	Adopted April 2021 for consultation End of consultation: 31 May 2021
EMA/CVMP/EWP/170208/2005	Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products	Adopted July 2021 for consultation End of consultation 30 September 2021
EMA/CVMP/52665/2020	Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted July 2021
EMA/CVMP/147926/2021	Overview of comments received on 'Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6' (EMA/CVMP/52665/2020)	Adopted September 2021

CVMP Pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/10418/2009-Rev.12	VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2021
EMA/CVMP/PhVWP/288284/2007 - Rev.13	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2021

CVMP Antimicrobials

Reference number	Document title	Status
EMA/CVMP/179874/2020	CVMP strategy on antimicrobials 2021-2025	Adopted January 2021
EMA/CVMP/AWP/842786/2015	Reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations in animals in the European Union: development of resistance and impact on human and animal health	Adopted February 2021
EMA/CVMP/383441/2005-Rev.1	Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances	Adopted June 2021
EMA/CVMP/143258/2021	Reflection paper on promoting the authorisation of alternatives to antimicrobial veterinary medicinal products in the EU	Adopted July 2021
EMA/CVMP/644209/2020	Overview of comments received on 'Reflection paper on promoting the authorisation of alternatives to antimicrobials in the EU' (EMA/CVMP/461776/2017)	Adopted July 2021

CVMP Immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/630533/2020	Concept paper for the development of a guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances	Adopted January 2021 for consultation. End of consultation: 31 March 2021

Reference number	Document title	Status
EMA/CVMP/IWP/674640/2020	Concept paper for the development of a guideline on data requirements for vaccine antigen master files (VAMF)	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/IWP/582191/2020	Concept paper for the development of a guideline on data requirements for vaccine platform technology master files (PTMF)	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/IWP/600275/2020	Concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD)	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/IWP/671155/2020	Concept paper on the provision of field efficacy studies in support of marketing authorisation applications for immunological veterinary medicinal products and on indications for veterinary vaccines	Adopted January 2021 for consultation. End of consultation: 31 March 2021
EMA/CVMP/59531/2020	Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/IWP/251741/2015	CVMP reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products	Adopted May 2021 for consultation End of consultation: 23 July 2021
EMA/CVMP/IWP/105506/2007 - Rev. 2	Guideline on data requirements for multi-strain dossiers for inactivated veterinary vaccines	Adopted June 2021 for consultation End of consultation 30 September 2021
EMA/CVMP/IWP/258755/2021	Guideline on data requirements for vaccine antigen master files (VAMF)	Adopted June 2021 for consultation End of consultation 30 September 2021

Reference number	Document title	Status
EMA/CVMP/IWP/284316/2021	Concept paper for the revision of the guideline on requirements for production and control of immunological veterinary medicinal products	Adopted June 2021 for consultation End of consultation 30 September 2021
EMA/CVMP/IWP/315887/2017	Guideline on data requirements for adjuvants in vaccines for veterinary use	Adopted July 2021
EMA/CVMP/IWP/30398/2019	Overview of comments received on 'Guideline on the use of adjuvanted veterinary vaccines' (EMA/CVMP/IWP/315887/2017)	Adopted July 2021
EMA/CVMP/IWP/299554/2021	Guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances	Adopted July 2021 for consultation End of consultation 29 October 2021
EMA/CVMP/IWP/283631/2021	Guideline on data requirements for vaccine platform technology master files (vPTMF)	Adopted July 2021 for consultation End of consultation 29 October 2021
EMA/CVMP/IWP/260956/2021	Guideline on clinical trials with immunological veterinary medicinal products	Adopted July 2021 for consultation End of consultation 29 October 2021
EMA/CVMP/59531/2020	Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6	Adopted July 2021
EMA/CVMP/IWP/251741/2015 Rev. 1	Reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products	Adopted September 2021

Reference number	Document title	Status
EMA/CVMP/147910/2021	Overview of comments received on 'Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6' (EMA/CVMP/59531/2020)	Adopted September 2021

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/ERA/632109/2014	Reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of veterinary medicinal products	Adopted February 2021
EMA/CVMP/ERA/173026/2021	Concept paper on the development of a guideline on the environmental risk assessment of veterinary medicinal products intended to be used in aquaculture	Adopted July 2021
EMA/CVMP/ERA/622045/2020	Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6	Adopted September 2021 for consultation End of consultation 17 December 2021
EMA/CVMP/ERA/87473/2021	Reflection paper on higher tier testing to investigate the effects of parasiticidal veterinary medicinal products on dung fauna	Adopted September 2021

CVMP Novel therapies and technologies

Reference number	Document title	Status
EMA/CVMP/NTWP/706123/2020	Mandate, objectives and rules of procedure for the CVMP Veterinary Novel Therapies & Technologies Working Party (NTWP)	Adopted March 2021

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

None.

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

[Topics covered by regular WPs are shown in the relevant thematic sections above]

Reference number	Document title	Status
EMA/635856/2020	Guideline on veterinary good pharmacovigilance practices (VGVP) Collection and recording of suspected adverse events for veterinary medicinal products	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/328998/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Controls and pharmacovigilance inspections	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/257136/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/307620/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Signal management	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/63454/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Veterinary pharmacovigilance communication	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/118227/2021	Guideline on veterinary good pharmacovigilance practices (VGVP) Annex: Glossary	Adopted June 2021 for consultation End of consultation 5 September 2021
EMA/CMDv/7381/2021	Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations	Adopted May 2021

None.

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/553776/2020	CVMP work plan 2021	Adopted January 2021
EMA/CVMP/235292/2020	Reflection paper on classification of a product as intended for a limited market and eligibility for authorisation according to Article 23 (Applications for limited markets)	Adopted February 2021 for consultation End of consultation: 15 May 2021
EMA/CVMP/235292/2020	Reflection paper on classification of a product as intended for a limited market and eligibility for authorisation according to Article 23 (Applications for limited markets)	Adopted July 2021
EMA/CVMP/147858/2021	Overview of comments received on 'Reflection paper on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)' (EMA/CVMP/235292/2020)	Adopted July 2021
EMA/CVMP/272194/2021	Form for classification of a veterinary medicinal product intended for a limited market according to Article 4 (29) and for eligibility for authorisation according to Article 23 of Regulation (EU) 2019/6	Adopted July 2021