21 July 2021
EMA/311250/2021
Veterinary Medicines Division

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

May 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.

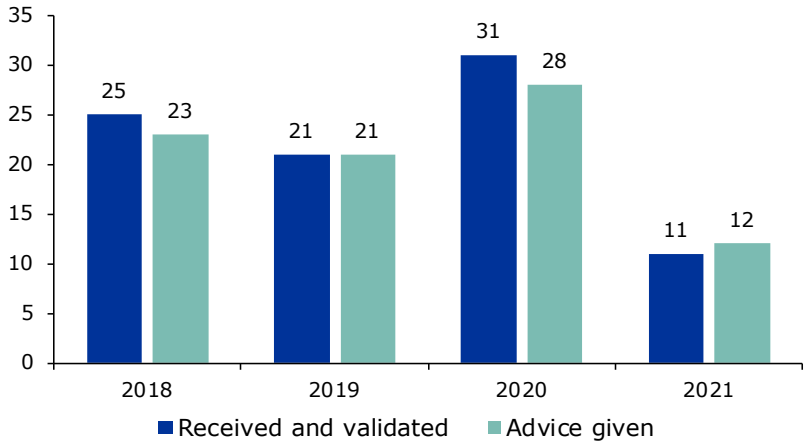
The purpose is to provide ongoing factual information. Commentaries and analysis are provided in the Agency's annual reports.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

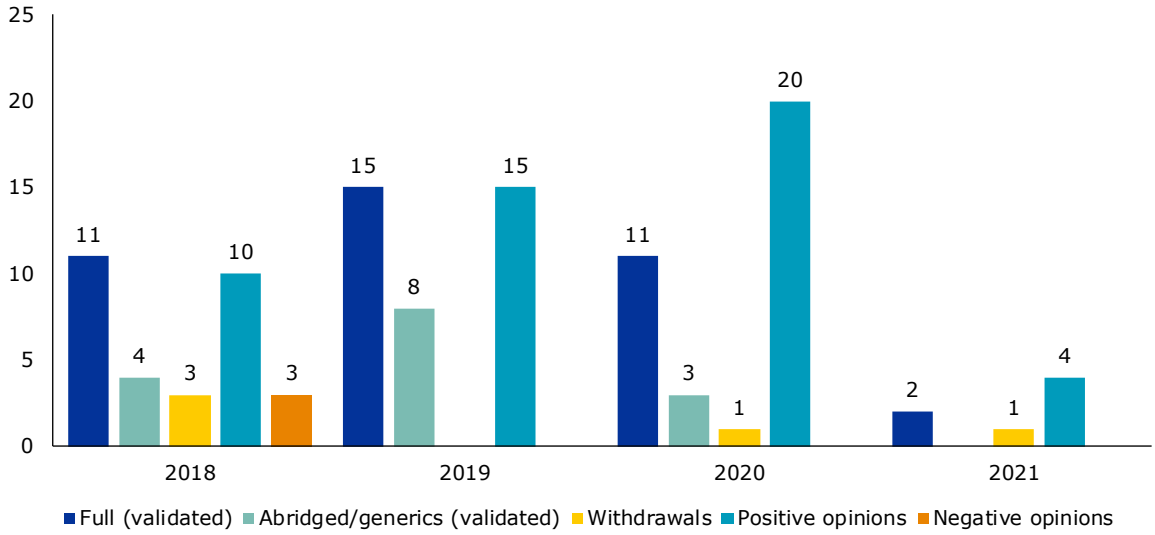
Scientific advice requests				
	2018	2019	2020	2021
Received and validated	25	21	31	**11**
Advice given	23	21	28	**12**

Scientific advice requests submitted and advice given



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

MAA submissions and outcomes



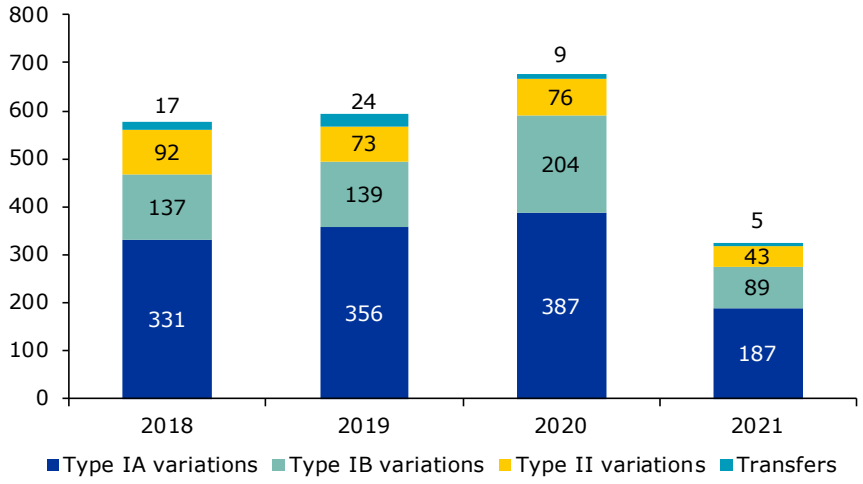
[1] Numbers for re-examinations or re-considerations (request by European Commission) of opinion are in brackets

Marketing authorisations[2]				
	2018	2019	2020	2021
Granted	9	19	19	**6**
Withdrawals	5	3	4	**1**
Refusals	1	0	0	**-**
Not renewed	2	0	3	**-**

Extensions — applications				
	2018	2019	2020	2021
Received and validated	1	2	2	**-**
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	**187**
Type-IB variations	137	139	204	**89**
Type-II variations	92	73	76	**43**
Transfers	17	24	9	**5**

Post-authorisation: submissions of variations and transfers



Renewals — applications				
	2018	2019	2020	2021
Received and validated	24	11	10	**3**
Positive opinions	15	19	14	**1**
Negative opinions	0	0	0	**-**

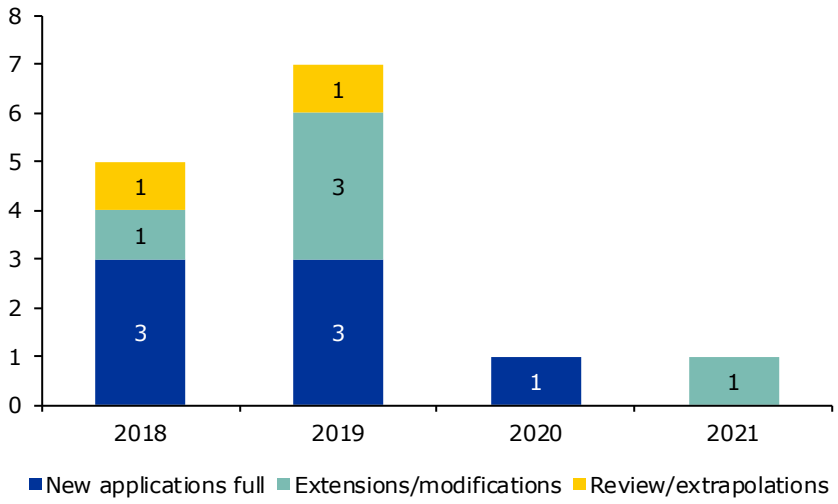
[2] Marketing authorisations are granted by the European Commission

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	1
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	-

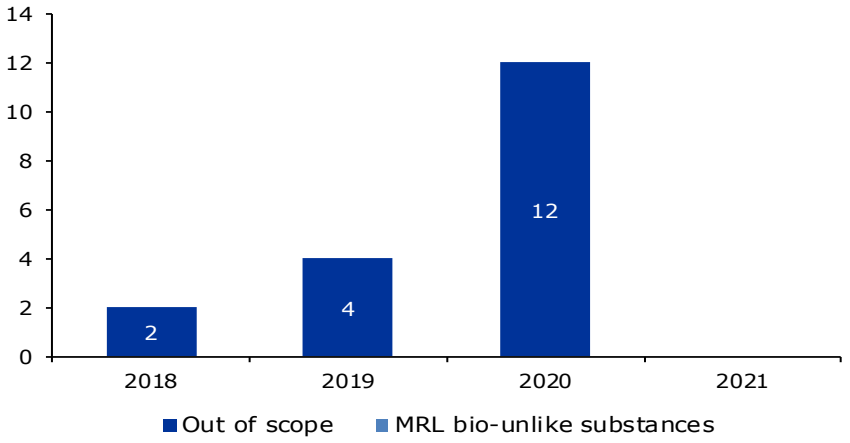
MRL submissions



[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.

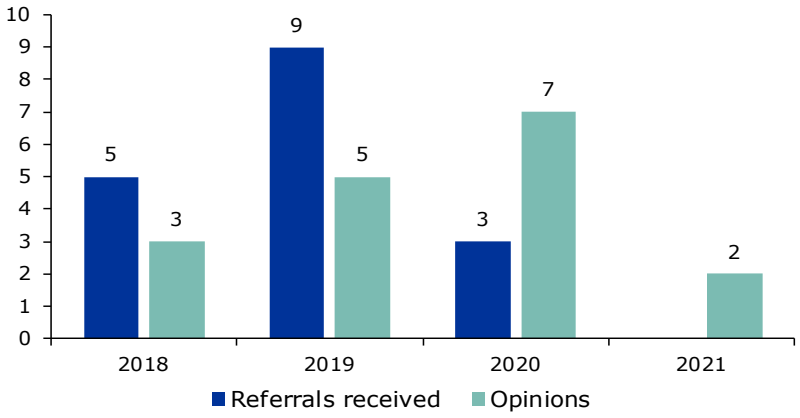
Other MRL-related submissions				
	2018	2019	2020	2021
Out of scope requests[8], of which				
Received	2	4	12	-
Agreed	1	3	9	-
Not agreed	0	1	1	-
Scientific advice recommended	2	0	1	**1**
Need for an MRL evaluation for 'chemical-unlike' biological substances[9], of which				
Received	-	-	-	-
MRL evaluation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

MRL-related submissions



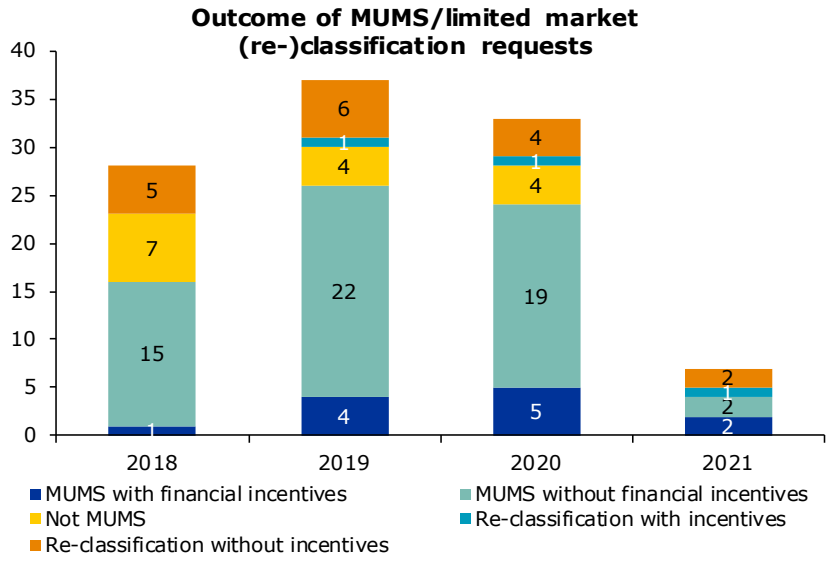
Arbitrations and referrals				
	2018	2019	2020	2021
Arbitrations and referrals received	5	9	3	-
Opinions[10]	3(1)	5	7	**2**

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**	**2**
MUMS/limited market without financial incentives	15	22	**19**	**2**
MUMS/limited market reclassification with financial incentives	0	1	**1**	**1**
MUMS/limited market reclassification without financial incentives	5	6	**4**	**2**
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

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 • 18/03/2021

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	• 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

None.

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

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

CVMP Pharmacovigilance

None.

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

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
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

Reference number	Document title	Status
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

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

CVMP Novel therapies and technologies

None.

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]

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

Reference number	Document title	Status
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