



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 March 2020
EMA/46356/2020
Veterinary Medicines Division

Monthly report on application procedures, guidelines and related documents for veterinary medicines January 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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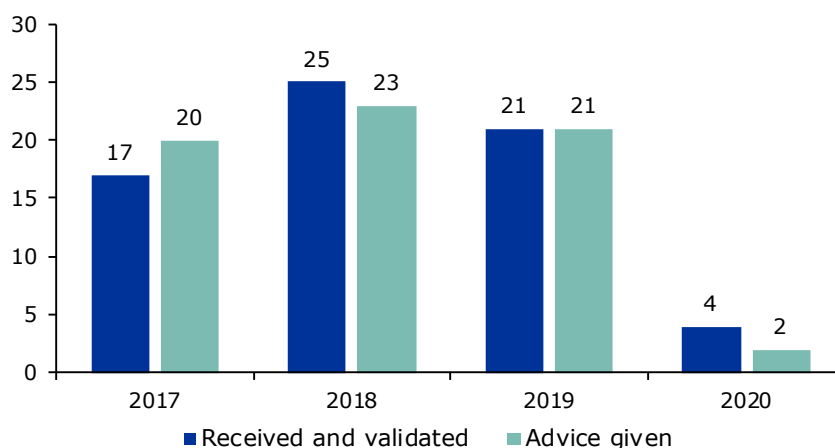
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Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

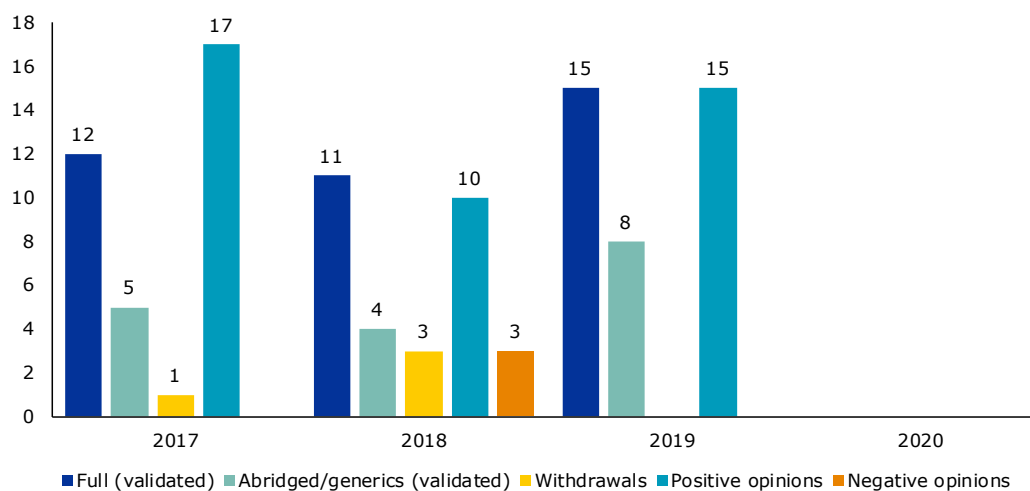
Scientific advice requests				
	2017	2018	2019	2020
Received and validated	17	25	21	4
Advice given	20	23	21	2

Scientific advice requests submitted and advice given



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

MMA submissions and outcomes

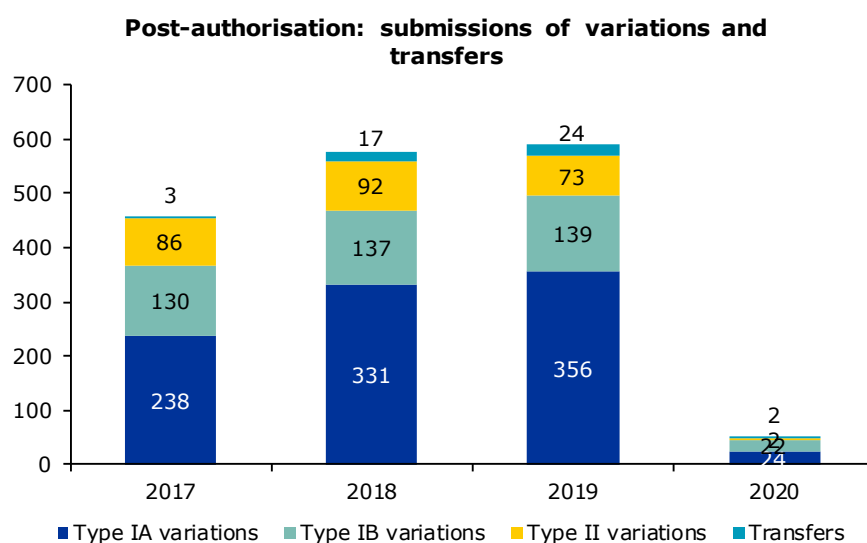


¹ Numbers for re-examinations or re-considerations (request by European Commission) of opinion are in brackets

Marketing authorisations²				
	2017	2018	2019	2020
Granted	18	9	19	2
Withdrawals	0	5	3	0
Refusals	0	1	0	0
Not renewed	0	2	0	0

Extensions – applications				
	2017	2018	2019	2020
Received and validated	5	1	2	0
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	24
Type-IB variations	130	137	139	22
Type-II variations	78	92	73	2
Transfers	3	17	24	2



Renewals – applications				
	2017	2018	2019	2020
Received and validated	9	24	11	2
Positive opinions	10	15	19	0
Negative opinions	0	0	0	0

² Marketing authorisations are granted by the European Commission

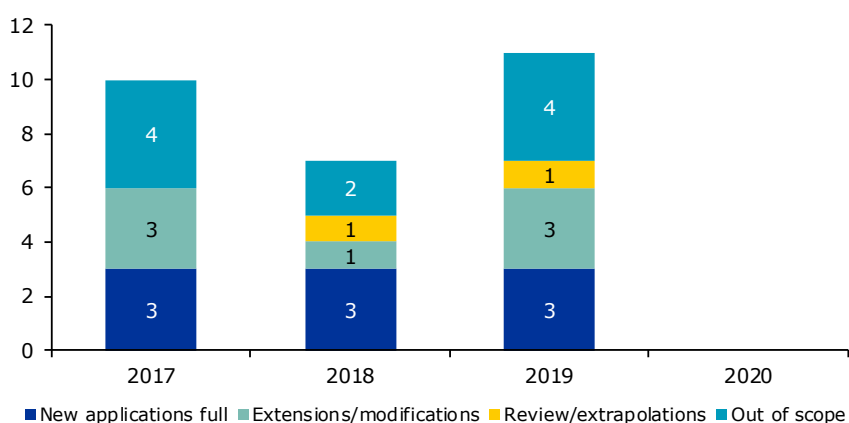
Establishment of MRLs for new substances ³ – applications				
	2017	2018	2019	2020
Received and validated	3	3	3	0
Withdrawals	2	2	0	0
Positive opinions ^{4,5}	4	1	2	0
Negative opinions	0	0	0	0

Extensions/modifications of MRLs ⁶ – applications				
	2017	2018	2019	2020
Received and validated	3	1	3	0
Withdrawals	0	0	0	0
Positive opinions ³	2	2	0	0
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 ³	0	1	1	0

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

MRL-related submissions



³ Establishment of MRLs for new substances under article 3 of Regulation (EC) No 470/2009.

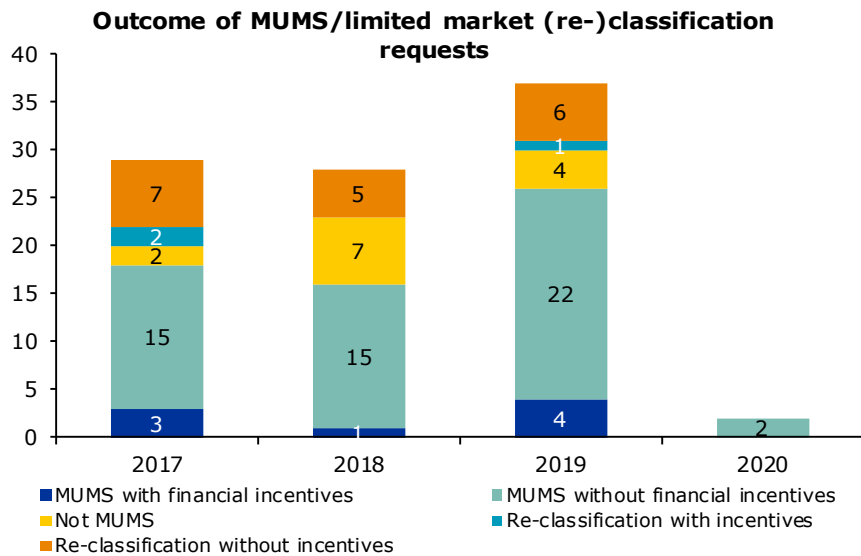
⁴ Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.

⁵ Re-examinations of opinions are indicated in brackets.

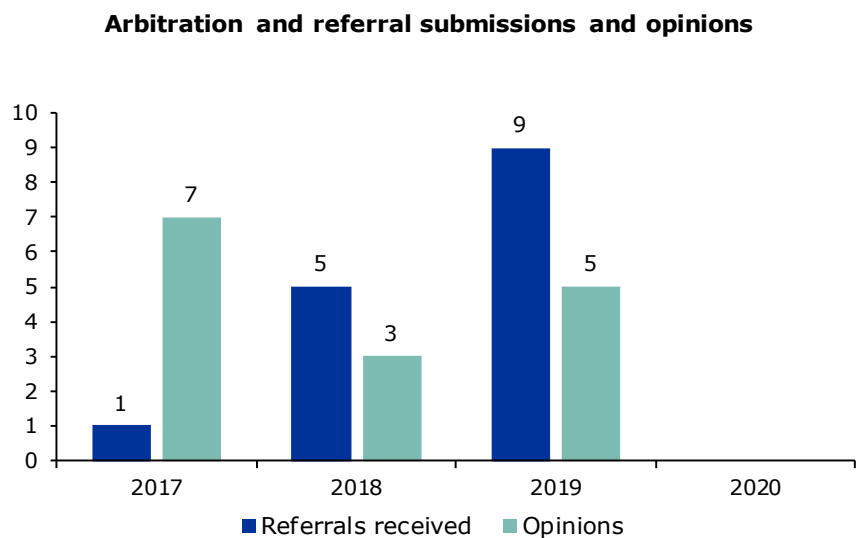
⁶ Extension or modification of MRLs under article 3 of Regulation (EC) No 470/2009.

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				
	2017	2018	2019	2020
MUMS/limited market with financial incentives	3	1	4	0
MUMS/limited market without financial incentives	15	15	22	2
MUMS/limited market reclassification with financial incentives	2	0	1	0
MUMS/limited market reclassification without financial incentives	7	5	6	0
Not MUMS/limited market	2	7	4	0



Arbitrations and referrals				
	2017	2018	2019	2020
Arbitrations and referrals received	1	5	9	0
Opinions ⁸	7(1)	3(1)	5	0



⁸ Re-examinations of opinions are in brackets.

CVMP opinions in 2020 on medicinal products for veterinary use

Positive opinions

Product <ul style="list-style-type: none">Invented nameINN/Common name	Marketing authorisation holder	Target species	Regulatory information <ul style="list-style-type: none">Procedure numberOpinion date
<ul style="list-style-type: none">None	<ul style="list-style-type: none">None	<ul style="list-style-type: none">None	<ul style="list-style-type: none">None

Negative opinions

Product <ul style="list-style-type: none">Invented nameINN/Common name	Applicant	Target species	Regulatory information <ul style="list-style-type: none">Procedure numberOpinion date
<ul style="list-style-type: none">None	<ul style="list-style-type: none">None	<ul style="list-style-type: none">None	<ul style="list-style-type: none">None

CVMP opinions in 2020 on establishment of MRLs

Positive opinions

Product <ul style="list-style-type: none">Substance	Target species	Regulatory information <ul style="list-style-type: none">Procedure numberOpinion date
<ul style="list-style-type: none">None	<ul style="list-style-type: none">None	<ul style="list-style-type: none">None

Arbitrations and referrals in 2020

Ongoing procedures

Type of procedure	Date <ul style="list-style-type: none">Clock startCVMP opinion	Product <ul style="list-style-type: none">Product nameINN
<ul style="list-style-type: none">Referral under Article 35 of Directive 2001/82/EC	<ul style="list-style-type: none">20/02/2019	<ul style="list-style-type: none">Betamox LA 150 mg/ml Suspension for Injection and its associated names, and generic products thereofAmoxicillin
<ul style="list-style-type: none">Referral under Article 34 of Directive 2001/82/EC	<ul style="list-style-type: none">17/07/2019	<ul style="list-style-type: none">Adjusol and its associated namesSulfadiazine and Trimethoprim

Type of procedure	Date <ul style="list-style-type: none"> • Clock start • CVMP opinion 	Product <ul style="list-style-type: none"> • Product name • INN
<ul style="list-style-type: none"> • Referral under Article 35 of Directive 2001/82/EC 	<ul style="list-style-type: none"> • 11/09/2019 	<ul style="list-style-type: none"> • Dinolytic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names and generic products thereof • Dinoprost tromethamine
<ul style="list-style-type: none"> • Referral under Article 34 of Directive 2001/82/EC 	<ul style="list-style-type: none"> • 11/09/2019 	<ul style="list-style-type: none"> • Ronaxan and its associated names • Doxycycline hyclate
<ul style="list-style-type: none"> • Referral under Article 35 of Directive 2001/82/EC 	<ul style="list-style-type: none"> • 09/10/2019 	<ul style="list-style-type: none"> • Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof • Azaperone
<ul style="list-style-type: none"> • Referral under Article 35 of Directive 2001/82/EC 	<ul style="list-style-type: none"> • 06/11/2019 	<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • Procedure under Article 45 of Regulation (EC) 726/2004 	<ul style="list-style-type: none"> • 07/11/2019 	<ul style="list-style-type: none"> • Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs • Porcine respiratory and reproductive syndrome (PRRS) 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

CVMP Safety

None.

CVMP Efficacy

None.

CVMP Pharmacovigilance

None.

CVMP Antimicrobials

None.

CVMP Immunologicals

None.

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

CVMP Novel therapies

None.

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

None.

General

None.