



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

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

### February 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.

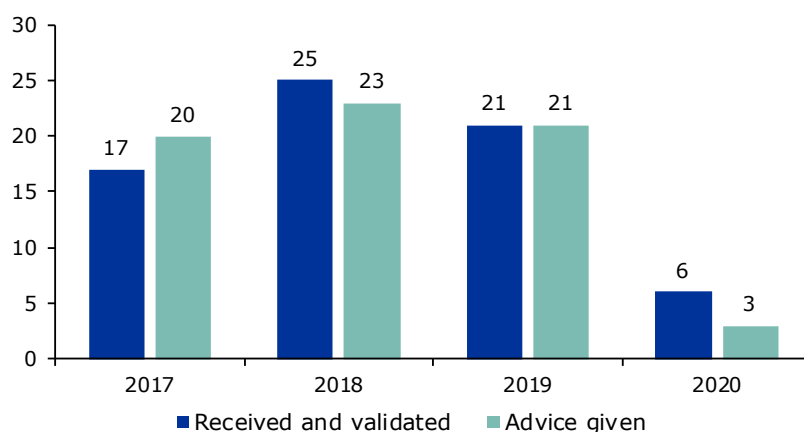


## Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

### Scientific advice requests

	2017	2018	2019	2020
Received and validated	17	25	21	<b>6</b>
Advice given	20	23	21	<b>3</b>

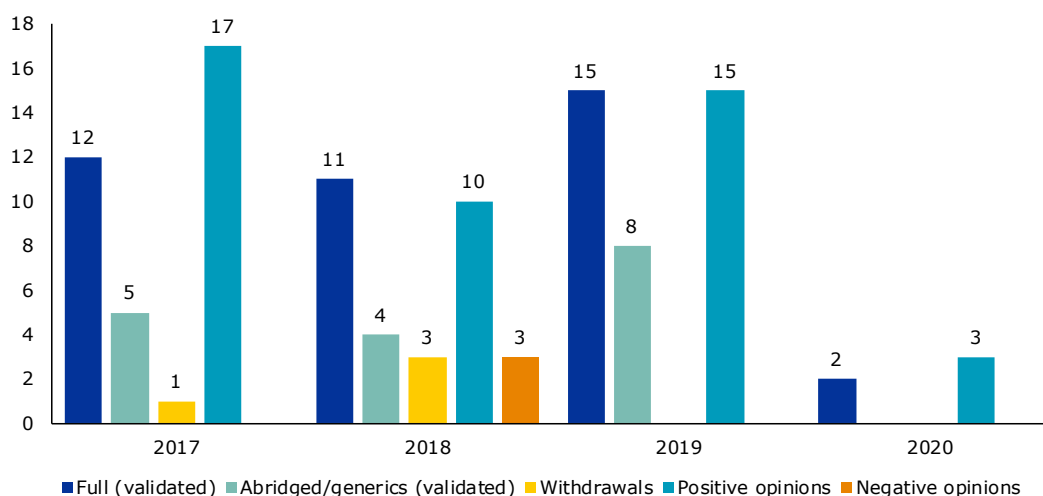
Scientific advice requests submitted and advice given



### Initial evaluation of marketing authorisations – applications (MAA)

	2017	2018	2019	2020
Full (validated)	12	11	15	<b>2</b>
Abridged/generics (validated)	5	4	8	<b>0</b>
Withdrawals of applications	1	3	0	<b>0</b>
Positive opinions <sup>1</sup>	17(1)	10	15(2)	<b>3</b>
Negative opinions <sup>1</sup>	0	3	(1)	<b>0</b>

MAA submissions and outcomes



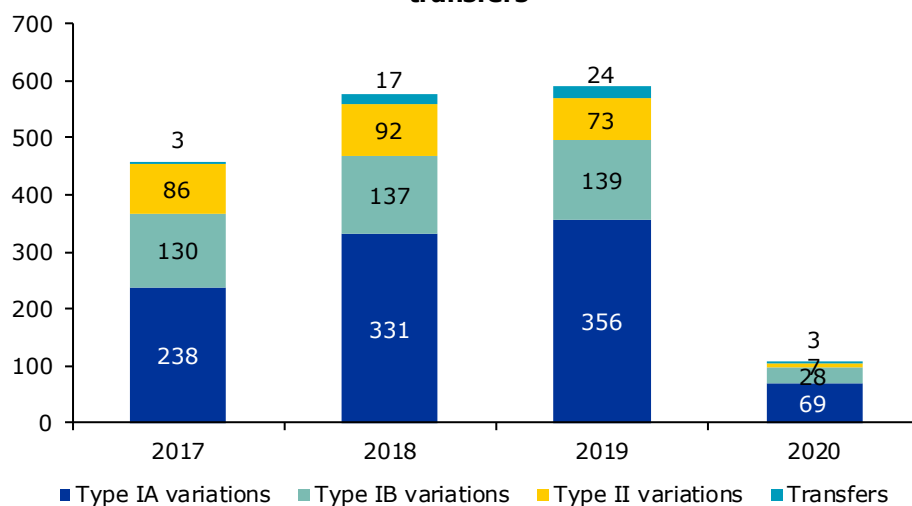
<sup>1</sup> Numbers for re-examinations or re-considerations (request by European Commission) of opinion are in brackets

Marketing authorisations <sup>2</sup>				
	2017	2018	2019	2020
Granted	18	9	19	2
Withdrawals	0	5	3	2
Refusals	0	1	0	0
Not renewed	0	2	0	0

Extensions — applications				
	2017	2018	2019	2020
Received and validated	5	1	2	1
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	69
Type-IB variations	130	137	139	28
Type-II variations	78	92	73	7
Transfers	3	17	24	3

**Post-authorisation: submissions of variations and transfers**



Renewals — applications				
	2017	2018	2019	2020
Received and validated	9	24	11	3
Positive opinions	10	15	19	3
Negative opinions	0	0	0	0

<sup>2</sup> Marketing authorisations are granted by the European Commission

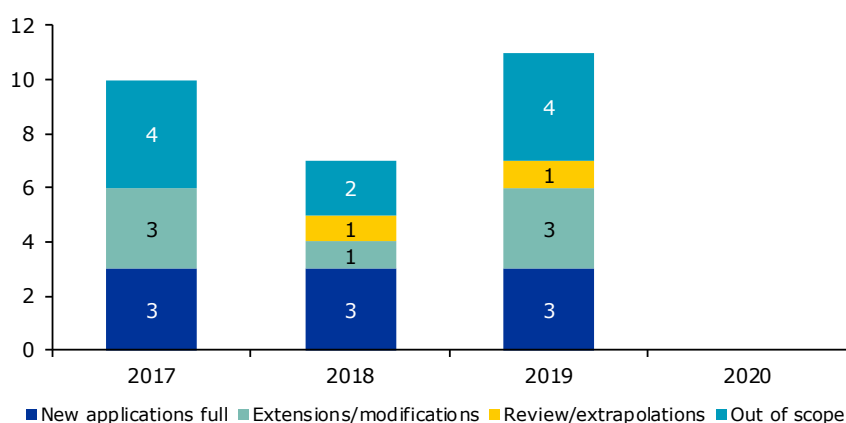
Establishment of MRLs for new substances <sup>3</sup> – applications				
	2017	2018	2019	2020
Received and validated	3	3	3	0
Withdrawals	2	2	0	0
Positive opinions <sup>4,5</sup>	4	1	2	1
Negative opinions	0	0	0	0

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

Review of opinions/extrapolations of MRLs <sup>7</sup>				
	2017	2018	2019	2020
Received and validated	0	1	1	0
Opinion <sup>3</sup>	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	1
Not agreed	0	0	1	0
Scientific advice recommended	1	2	0	0

**MRL-related submissions**



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

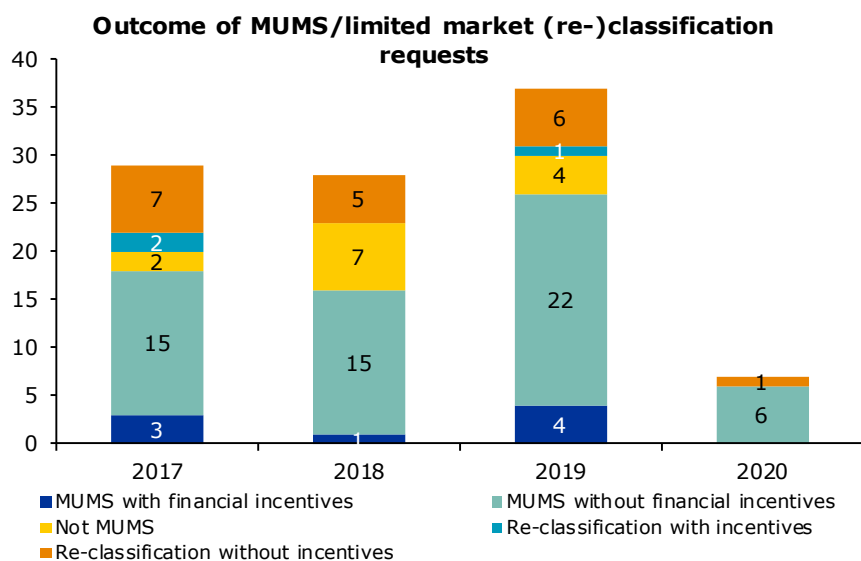
<sup>4</sup> Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.

<sup>5</sup> Re-examinations of opinions are indicated in brackets.

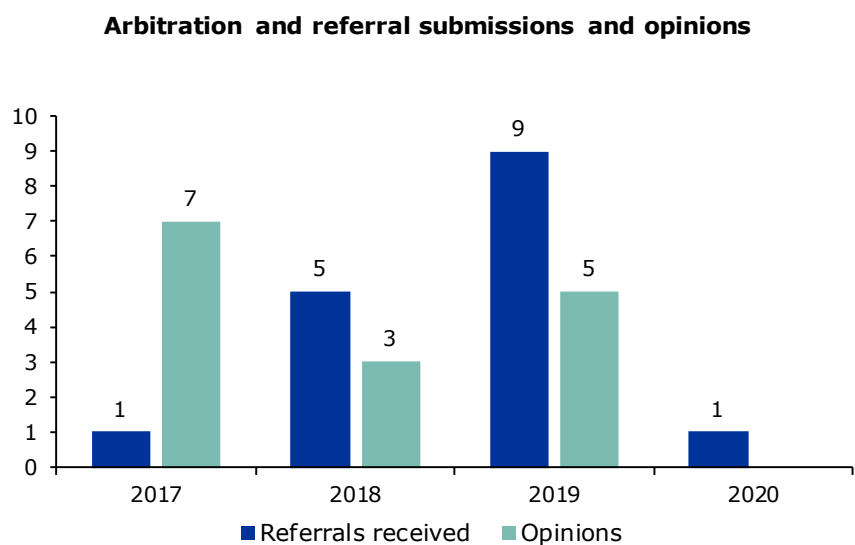
<sup>6</sup> Extension or modification of MRLs under article 3 of Regulation (EC) No 470/2009.

<sup>7</sup> 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	6
MUMS/limited market reclassification with financial incentives	2	0	1	0
MUMS/limited market reclassification without financial incentives	7	5	6	1
Not MUMS/limited market	2	7	4	0



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



<sup>8</sup> Re-examinations of opinions are in brackets.

## CVMP opinions in 2020 on medicinal products for veterinary use

### Positive opinions

Product	Marketing authorisation holder	Target species	Regulatory information
<ul style="list-style-type: none"> <li>Invented name</li> <li>INN/Common name</li> </ul>			<ul style="list-style-type: none"> <li>Procedure number</li> <li>Opinion date</li> </ul>
<ul style="list-style-type: none"> <li>Tulaven</li> <li>Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>CEVA Santé Animale</li> </ul>	<ul style="list-style-type: none"> <li>Cattle, Pigs, Sheep</li> </ul>	<ul style="list-style-type: none"> <li>EMA/V/C/005153/0000</li> <li>20/02/2020</li> </ul>
<ul style="list-style-type: none"> <li>Tulissin</li> <li>Tulathromycin</li> </ul>	<ul style="list-style-type: none"> <li>Virbac S.A.</li> </ul>	<ul style="list-style-type: none"> <li>Cattle, Pigs, Sheep</li> </ul>	<ul style="list-style-type: none"> <li>EMA/V/C/005073/0000</li> <li>20/02/2020</li> </ul>
<ul style="list-style-type: none"> <li>Vectormune FP ILT + AE</li> <li>Fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live)</li> </ul>	<ul style="list-style-type: none"> <li>Ceva-Phylaxia Co. Ltd</li> </ul>	<ul style="list-style-type: none"> <li>Chickens</li> </ul>	<ul style="list-style-type: none"> <li>EMA/V/C/005077/0000</li> <li>20/02/2020</li> </ul>

### Negative opinions

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

## CVMP opinions in 2020 on establishment of MRLs

### Positive opinions

Product	Target species	Regulatory information
<ul style="list-style-type: none"> <li>Substance</li> </ul>		<ul style="list-style-type: none"> <li>Procedure number</li> <li>Opinion date</li> </ul>
<ul style="list-style-type: none"> <li>Bupivacaine</li> </ul>	<ul style="list-style-type: none"> <li>Pigs</li> </ul>	<ul style="list-style-type: none"> <li>EMA/V/MRL/005009/FULL/0001</li> <li>20/02/2020</li> </ul>

## Arbitrations and referrals in 2020

### Ongoing procedures

Type of procedure	Date <ul style="list-style-type: none"> <li>Clock start</li> <li>CVMP opinion</li> </ul>	Product <ul style="list-style-type: none"> <li>Product name</li> <li>INN</li> </ul>
<ul style="list-style-type: none"> <li>Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>20/02/2019</li> </ul>	<ul style="list-style-type: none"> <li>Betamox LA 150 mg/ml Suspension for Injection and its associated names, and generic products thereof</li> <li>Amoxicillin</li> </ul>
<ul style="list-style-type: none"> <li>Referral under Article 34 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>17/07/2019</li> </ul>	<ul style="list-style-type: none"> <li>Adjusol and its associated names</li> <li>Sulfadiazine and Trimethoprim</li> </ul>
<ul style="list-style-type: none"> <li>Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>11/09/2019</li> </ul>	<ul style="list-style-type: none"> <li>Dinolitic 12.5 mg/ml and 5 mg/ml solutions for injection, and associated names and generic products thereof</li> <li>Dinoprost tromethamine</li> </ul>
<ul style="list-style-type: none"> <li>Referral under Article 34 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>11/09/2019</li> </ul>	<ul style="list-style-type: none"> <li>Ronaxan and its associated names</li> <li>Doxycycline hyclate</li> </ul>
<ul style="list-style-type: none"> <li>Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>09/10/2019</li> </ul>	<ul style="list-style-type: none"> <li>Stresnil 40 mg/ml solution for injection for pigs and associated names, and generic products thereof</li> <li>Azaperone</li> </ul>
<ul style="list-style-type: none"> <li>Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>06/11/2019</li> </ul>	<ul style="list-style-type: none"> <li>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</li> <li>Tiamulin hydrogen fumarate</li> </ul>
<ul style="list-style-type: none"> <li>Procedure under Article 45 of Regulation (EC) 726/2004</li> </ul>	<ul style="list-style-type: none"> <li>07/11/2019</li> </ul>	<ul style="list-style-type: none"> <li>Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs</li> <li>Porcine respiratory and reproductive syndrome (PRRS) virus vaccine (live)</li> </ul>
<ul style="list-style-type: none"> <li>Referral under Article 35 of Directive 2001/82/EC</li> </ul>	<ul style="list-style-type: none"> <li>19/02/2020</li> </ul>	<ul style="list-style-type: none"> <li>Valbazen 100 mg/ml Total Spectrum Wormer oral suspension and associated names, including its generic/hybrid products</li> <li>Albendazole</li> </ul>

## 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

Reference number	Document title	Status
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.