13 January 2017
EMA/872789/2016
Veterinary Medicines Division

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

December 2016

This report, which is updated every month, provides current 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 only to provide ongoing factual information. Commentaries and analysis are provided in the Agency's annual reports.

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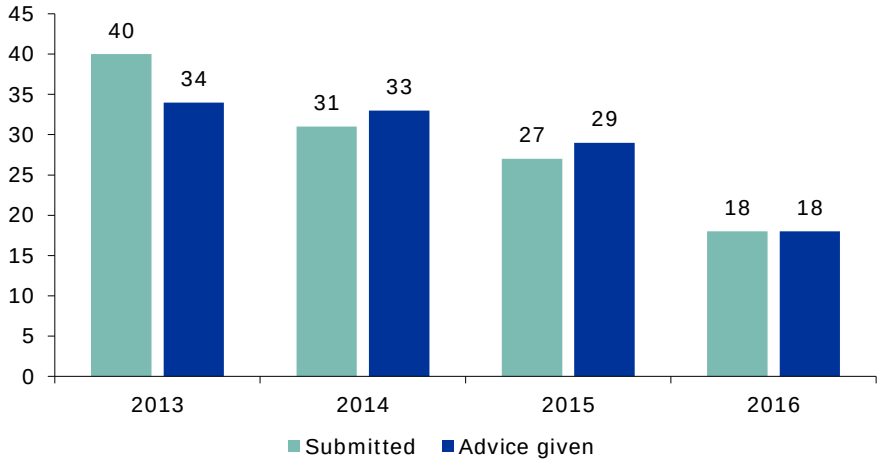
Statistics on pre- and post-authorisation applications for medicinal products for veterinary use

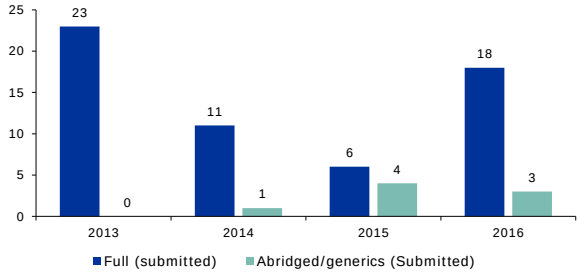
Scientific advice requests	2013	2014	2015	2016
Submitted and validated	40	31	27	**18**
Advice given	34	33	29	**18**

Scientific advice requests submitted and advice given

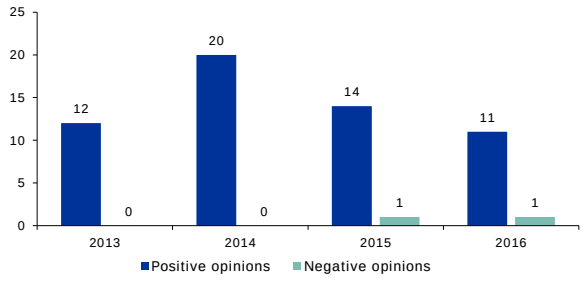


Initial evaluation of marketing authorisation applications	2013	2014	2015	2016
Full (submitted)	23	11	6	**18**
Abridged/generics (submitted)	0	1	4	**3**
Withdrawals	0	3	0	**1**
Positive opinions	12	20	14	**11**
Negative opinions	0	0	1	**1**

Pre-authorisation: submissions of MA applications by type



Pre-authorisation: outcome of the evaluation of MA applications

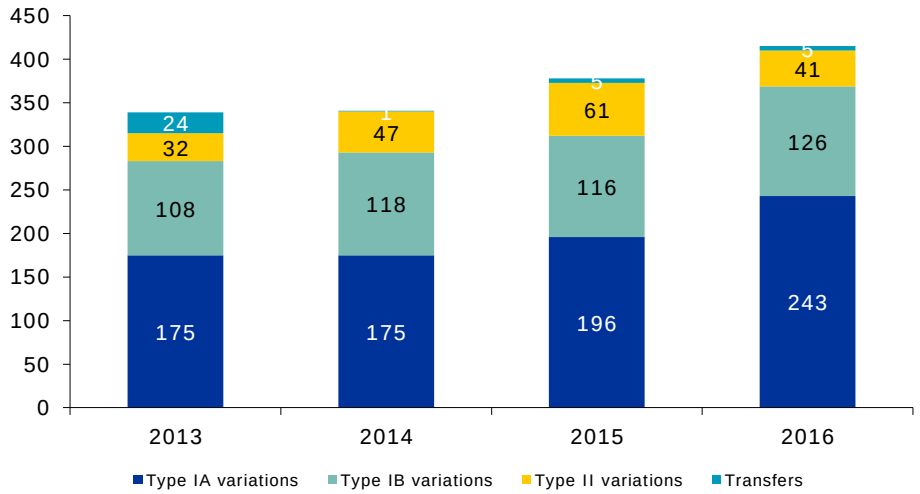


Marketing authorisations				
	2013	2014	2015	2016
Granted	13	19	17	**7**
Withdrawals	3	1	3	**1**
Refusal	0	0	1	**0**
Not renewed	0	0	0	**1**

Extensions — applications				
	2013	2014	2015	2016
Submitted	5	6	3	**3**
Withdrawals	0	1	0	**0**
Positive opinions	9	2	6	**5**
Negative opinions	0	0	1	**0**

Variations — applications submitted				
	2013	2014	2015	2016
Type-IA variations	175	175	196	**243**
Type-IB variations	108	118	116	**126**
Type-II variations	32	47	61	**41**
Transfers	24	1	5	**5**

Post-authorisation: variations and transfers submitted



Renewals — applications				
	2013	2014	2015	2016
Submitted	16	10	24	**13**
Positive opinions	14	15	19	**14**
Negative opinions	0	0	0	**0**

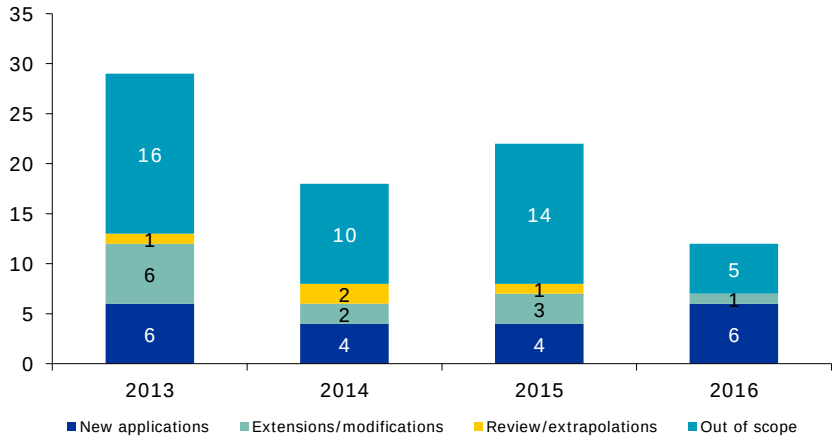
Establishment of MRLs for new substances[1] — applications	2013	2014	2015	2016
Submitted	6	4	4	**6**
Withdrawals	1	0	1	**0**
Positive opinions [2,3]	4	4	3 (1)	**2**
Negative opinions	0	0	0	**0**

Extensions / modifications of MRLs[4] — applications	2013	2014	2015	2016
Submitted	6	2	3	**1**
Withdrawals	0	0	0	**1**
Positive opinions [2]	4	8	2	**3**
Negative opinions	0	0	0	**0**

Review of opinions / extrapolations of MRLs[5] – requests from Commission or Member States	2013	2014	2015	2016
Submitted	1	2	1	**0**
Opinion [2]	4	2	3	**0**

Substances considered as not falling within the scope of Regulation (EC) No 470/2009 — requests	2013	2014	2015	2016
Submitted	16	10	14	**4**
Agreed	9	9	18	**3**
Not agreed	2	1	2	**0**
Scientific advice recommended	6	1	1	**1**

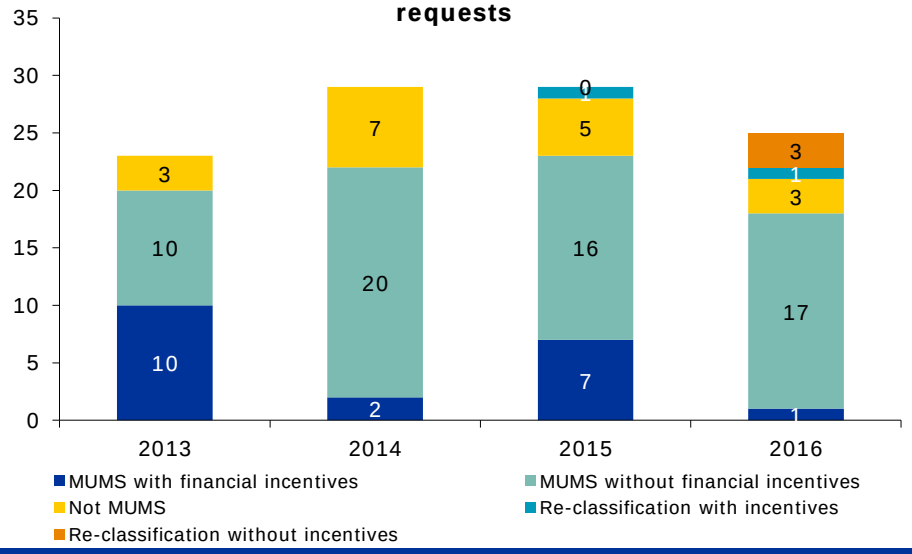
MRL-related submissions



[1] Establishment of MRLs for new substances under article 3 of Regulation (EC) No 470/2009.
[2] Including opinions recommending the extension of the expiry date for provisional MRLs or definitive MRLs for substances previously with provisional MRLs.
[3] Re-examinations of opinions are indicated in brackets.
[4] Extension or modification of MRLs under article 3 of Regulation (EC) No 470/2009.
[5] Review of opinions under article 11 of Regulation (EC) No 470/2009 or requests under article 27 of Regulation (EC) No 470/2009.

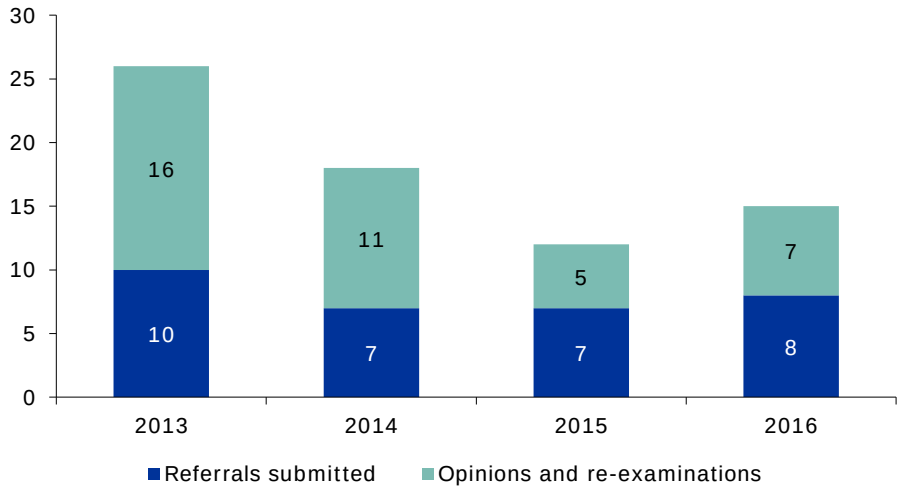
MUMS/limited market (re)classification requests — outcome	2013	2014	2015	2016
MUMS/limited market with financial incentives	10	2	6	**1**
MUMS/limited market without financial incentives	10	20	16	**17**
MUMS/limited market reclassification with financial incentives[6]	---	0	1	**1**
MUMS/limited market reclassification without financial incentives [6]	---	0	0	**3**
Not MUMS/limited market	3	7	5	**3**

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



Arbitrations and referrals	2013	2014	2015	2016
Arbitrations and referrals submitted	10	7	7	**8**
Opinions[7]	13 (3)	11 (1)	5	**7**

Arbitrations and referrals submitted and opinions



[6] For re-classification the first year available is 2014.
[7] Re-examinations of opinions are in brackets.

CVMP opinions in 2016 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
• **Evalon** • Coccidiosis vaccine (live) for chickens	• LABORATORIOS HIPRA, S.A.	• Chickens	• EMEA/V/C/004013/0000 • 18/02/2016
• **Letifend** • Canine leishmaniasis vaccine (recombinant protein)	• Laboratorios LETI, S.L.U.	• Dogs	• EMEA/V/C/003865/0000 • 18/02/2016
• **CLYNAV** • Salmon pancreas disease vaccine (recombinant DNA plasmid)	• Elanco Europe Ltd	• Atlantic salmon	• EMEA/V/C/002390/0000 • 21/04/2016
• **Sevohale**[8] • Sevoflurane	• Chanelle Pharmaceuticals Manufacturing Limited	• Dogs	• EMEA/V/C/004239/0000 • 21/04/2016
• **Sedadex** • Dexmedetomidine hydrochloride	• Le Vet Beheer B.V	• Dogs, cats	• EMEA/V/C/004202/0000 • 16/06/2016
• **Eravac** • Rabbit haemorrhagic disease vaccine	• Laboratorios Hipra, S.A.	• Rabbits	• EMEA/V/C/004239/0000 • 14/07/2016
• **Cepedex** • Dexmedetomidine	• CP-Pharma Handelsgesellschaft mbH	• Dogs, cats	• EMEA/V/C/004376/0000 • 06/10/2016
• **HALAGON** • Halofuginone	• Emdoka BVBA	• Newborn calf	• EMEA/V/C/004201/0000 • 06/10/2016

[8] Previously Sevocalm

Product • Invented name • INN/Common name	Marketing authorisation holder	Target species	Regulatory information • Procedure number • Opinion date
• **VarroMed** • Oxalic acid dihydrate/Formic acid	• BeeVital GmbH	• Honey bees	• EMEA/V/C/002723/0000 • 06/10/2016
• **Coliprotec F4/F18** • Porcine post-weaning diarrhoea vaccine (live)	• Prevtec Microbia GmbH	• Pigs	• EMEA/V/C004225/0000 • 10/11/2016
• **Stronghold Plus** • Selamectin/Sarolaner	• Zoetis Belgium SA	• Cats	• EMEA/V/C004194/0000 • 08/12/2016

CVMP opinions in 2016 on establishment of MRLs

Positive opinions

Product • Substance	Target species	Regulatory information • Procedure number • Opinion date
• Hydrocortisone aceponate	• All ruminants and *Equidae*	• EMEA/V/MRL/002993/FULL/0002 • 18/02/2016
• Monepantel	• Bovine	• EMEA/V/MRL/003200/EXTN/0003 • 19/05/2016
• Aluminium salicylate	• Bovine, caprine, *Equidae* and rabbits	• EMEA/V/MRL/003298/MODF/0004 • 14/07/2016
• Gamithromycin	• All ruminants except bovine	• EMEA/V/MRL/003158/EXTN/0003 • 14/07/2016
• Fluralaner	• Poultry	• EMEA/V/MRL/004380/FULL/0001 • 06/10/2016

Guidelines and working documents in 2016

CVMP quality

Reference number	Document title	Status
EMA/CVMP/QWP/128710/2004 – Rev.1	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)
EMA/CHMP/CVMP/QWP/850374/2015	Draft guideline on the sterilisation of the medicinal product, active substance, excipient and primary container.	Adopted for consultation February 2016 (End of consultation 13 October 2016)
[Published on EMA website]	Questions and Answers (Q&A) on the data requirements for sterilisation processes of primary packaging material subsequently used in an aseptic manufacturing process	Adopted February 2016
[Published on EMA website]	Questions and Answers (Q&A) relating to the SPC guideline for antimicrobials, in regard to suitable pack sizes for antimicrobials	Adopted February 2016
EMEA/CVMP/271/01-Rev.1	Revised note for guidance on limitations to the use of ethylene oxide in the manufacture of medicinal products	Noted March 2016
EMA/CHMP/CVMP/QWP/37330/2016	Draft reflection paper on the dissolution specification for generic oral immediate release products	Adopted for consultation April 2016 (End of consultation 13 August 2016)
[Published on EMA website]	Monthly report on application procedures guidelines and related documents for veterinary medicines July 2016	Adopted June 2016
EMA/CVMP/QWP/3629/2016	Draft reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances in marketing authorisation applications for veterinary medicinal products	Adopted for consultation July 2016 (End of consultation to be confirmed)

Reference number	Document title	Status
[Published on EMA website]	Questions and Answers on the deletion of a non-significant specification parameter	Adopted October 2016
EMA/CVMP/QWP/637000/2016	Guideline on the chemistry of active substances	Adopted for consultation November 2016 (End of consultation to be confirmed)
EMA/CHMP/CVMP/QWP/70278/2012-Rev.1, Corr.1	Guideline on process validation for finished products - information and data to be provided in regulatory submissions	Adopted November 2016
[Published on EMA website]	Questions and Answers on removal of a general heavy metals test from a specification	Adopted December 2016
[Published on EMA website]	Questions and Answers on improving the understanding of normal operating ranges, proven acceptable ranges, design spaces and normal variability of process parameters	Adopted December 2016
EMA/CVMP/QWP/128710/2004 – Rev.1	Guideline on quality data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted December 2016

CVMP safety

Reference number	Document title	Status
EMA/CVMP/SWP/66781/2005 – Rev.1	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)
EMA/CVMP/SWP/721059/2014	Draft guideline on user safety of topically administered veterinary medicinal products	Adopted for consultation June 2016 (End of consultation 31 December 2016)
EMA/CVMP/QWP/3629/2016	Draft guideline on approach towards harmonisation of withdrawal periods	Adopted for consultation July 2016 (End of consultation 31 January 2017)

Reference number	Document title	Status
EMA/CVMP/SWP/66781/2005 – Rev.1	Guideline on safety and residue data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted December 2016

CVMP efficacy

Reference number	Document title	Status
EMA/CVMP/11490/2016	Draft concept paper for the revision on the guideline for the conduct of pharmacokinetic studies in target animal species (EMEA/CVMP/133/99-Final)	Adopted for consultation January 2016 (End of consultation 31 March 2016)
EMA/CVMP/EWP/117899/2004 – Rev.1)	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)
EMA/CVMP/344/1999-Rev.2	Revised draft guideline on the conduct of efficacy studies for intramammary products for use in cattle	Adopted for second consultation February 2016 (End of consultation 31 May 2016)
CVMP/EWP/573536/2013	Revised reflection paper on anthelmintic resistance	Adopted for second consultation April 2016 (End of consultation 31 July 2016)
EMA/CVMP/EWP/707453/2015	Concept paper for the revision of the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2/2007)	Adopted for consultation April 2016 (End of consultation 31 July 2016)
EMA/CVMP/EWP/706095/2015	Concept paper for the revision of the Guideline on anticoccidials for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a Vol.7)	Adopted for consultation July 2016 (End of consultation 31 February 2016)
CVMP/EWP/005/2000-Rev.3	Revised guideline on the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats	Adopted July 2016

Reference number	Document title	Status
EMA/CVMP/EWP/707573/2015	Concept paper on the revision of the guideline for veterinary medicinal products for zootechnical purposes	Adopted for consultation December 2016 (End of consultation 31 March 2017)
EMA/CVMP/EWP/707299/2015	Concept paper for the revision of the guideline on veterinary medicinal products for fluid therapy in case of diarrhoea	Adopted for consultation December 2016 (End of consultation 31 March 2017)
EMA/CVMP/EWP/117899/2004–Rev.1	Guideline on efficacy and target animal safety data requirements for veterinary medicinal products intended for minor use or minor species (MUMS)/limited market	Adopted December 2016

CVMP pharmacovigilance

Reference number	Document title	Status
EMA/CVMP/PhVWP/357539/2015	Draft reflection paper on non-spontaneous adverse event reports	Adopted for consultation May 2016 (End of consultation 31 August 2016)
EMA/CVMP/90241/2009-Rev.8	CVMP combined VeDDRA list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products	Adopted June 2016
EMA/CVMP/PhVWP/288284/2007-Rev.9	Guidance notes on the use of VeDDRA terminology for reporting suspected adverse reactions in animals and humans	Adopted June 2016
[Published on EMA website]	Questions and Answers on expressing the frequency of adverse reactions within the product information	Adopted July 2016

CVMP antimicrobials

Reference number	Document title	Status
EMA/CVMP/627/01-Rev.1	Revised guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Adopted January 2016

Reference number	Document title	Status
EMA/231573/2016	Updated advice on the use of colistin in animals within the European Union	Adopted July 2016
EMA/CVMP/AWP/161553/2016	Concept paper for revision of the current guideline on the summary of product characteristics for antimicrobial products	Adopted for consultation July 2016 (End of consultation 31 October 2016)
EMA/CVMP/209189/2015	CVMP strategy on antimicrobials 2016-2020	Adopted October 2016

CVMP immunologicals

Reference number	Document title	Status
EMA/CVMP/IWP/123243/2006 – Rev.3).	Draft revised guideline on data requirements for veterinary medicinal products intended for MUMS/limited market	Adopted for consultation January 2016 (End of consultation 31 July 2016)
EMA/CVMP/IWP/867401/2015	Concept paper on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use	Adopted for consultation April 2016 (End of consultation 31 July 2016)
EMA/CVMP/IWP/49593/2013	CVMP reflection paper on the risks that should be considered prior to the use of unauthorised vaccines in emergency situations	Adopted September 2016
EMA/CVMP/IWP/867388/2015	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 for consultation September 2016 (End of consultation 31 December 2016)
EMA/CVMP/IWP/867395/2015	Concept paper for the revision of the note for guidance on the use of adjuvanted veterinary vaccines	Adopted for consultation September 2016 (End of consultation 31 December 2016)
EMA/CVMP/IWP/206555/2010-Rev.1	Guideline on requirements for the production and control of immunological veterinary medicinal products	Adopted December 2016

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 December 2016

CVMP environmental risk assessment

Reference number	Document title	Status
EMA/CVMP/448211/2015	Reflection paper on the authorisation of veterinary medicinal products containing (potential) Persistent Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances	Adopted for consultation February 2016 (End of consultation 31 May 2016)
EMA/CVMP/ERA/349254/2014	Reflection paper on poorly extractable and/or non-radiolabelled substances	Adopted March 2016
EMA/CVMP/ERA/689041/2015	Draft guideline on the plant testing strategy for veterinary medicinal products	Adopted for consultation May 2016 (End of consultation 30 November 2016)
[Published on EMA website]	Revised Questions and Answers document in support of the guidance on the implementation of CVMP Guideline on Environmental Impact Assessment for Veterinary Medicinal Products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	Adopted July 2016
EMA/CVMP/ERA/409350/2010	Draft guideline on the higher tier testing of veterinary medicinal products to dung fauna	Adopted for consultation July 2016 (End of consultation 31 January 2017)

CVMP novel therapies

Reference number	Document title	Status
EMA/CVMP/ADVENT/226871/2015	Problem statement on monoclonal antibodies intended for veterinary use	Adopted for consultation February 2016 (End of consultation 15 May 2016)
EMA/CVMP/ADVENT/276476/2015	Problem statement on sterility in relation to stem cell products intended for veterinary use	Adopted for consultation February 2016 (End of consultation 15 May 2016)
EMA/CVMP/ADVENT/174610/2016	Problem statement on stem cells-based products; specific question on extraneous agents for veterinary use	Adopted for consultation June 2016 (End of consultation 30 September 2016)
EMA/CVMP/ADVENT/207268/2016	Problem statements on stem cell-based products for veterinary use: Specific questions on tumorigenicity	Adopted for consultation June 2016 (End of consultation 30 September 2016)
EMA/CVMP/ADVENT/193811/2016	Problem statement on stem cell - based products for veterinary use: Specific questions on target animal safety	Adopted for consultation June 2016 (End of consultation 30 September 2016)

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

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/164002/2016	Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs	Adopted for consultation April 2016 (End of consultation 31 October 2016)
EMA/CHMP/CVMP/JEG-3Rs/94436/2014	Draft guideline for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs	Adopted for consultation July 2016 (End of consultation 31 January 2017)
EMA/CHMP/CVMP/JEG-3Rs/677407/2015	Report on the review and update of European Medicines Agency (the Agency) guidelines to implement best practice with regard to 3Rs in regulatory testing of medicinal products	Adopted for consultation July 2016 (End of consultation 31 January 2017)

Reference number	Document title	Status
EMA/CHMP/CVMP/JEG-3Rs/450091/2012	Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches	Adopted December 2016

General

Reference number	Document title	Status
EMA/CVMP/VICH/582610/2009	VICH GL50: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use	Adopted for consultation following the sign-off by the VICH Steering Committee (End of consultation 1 August 2016)
EMA/CVMP/VICH/313610/2013	VICH GL55: Revised guideline on Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use	Adopted for consultation following the sign-off by the VICH Steering Committee (End of consultation 1 August 2016)
EMA/CVMP/VICH/699251/2010	VICH GL54: Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish an acute reference dose (ARfD)	Adopted December 2016