

## Part IV Pre-Clinical and Clinical Trial

Written by Eva Vernerová - Last Updated Thursday, 02 March 2017 10:19

---

The particulars and documents, which shall accompany applications for marketing authorisations pursuant to the third indent of Article 12(3)(j) shall be submitted in accordance with the requirements of Annex I of Directive 2001/82/EC. The specific efficacy guidelines are published on the EMEA website under:

<http://www.emea.europa.eu/htms/vet/vetguidelines/efficacy.htm>

### General

Název	Číslo	Datum platnosti	Zdroj	Poznám
Fixed combination products	<a href="#">EMA/CVMP/83804/05</a>	July 2007	EMEA	
Statistical principles for veterinary clinical trials	<a href="#">EMA/CVMP/816/00</a>	December 2001	EMEA	
VICH GL9: Good clinical practices	<a href="#">EMA/CVMP/VICH/595/98</a>	July 2000	EMEA	

### Pre-clinical

Název	Číslo	Datum platnosti	Zdroj	Poznám
Evaluation of the safety of veterinary medicinal products for target animals	<a href="#">7AE2a Volume 7</a>	September 1994	EMEA	
VICH GL43: Target Animal Safety: Pharmaceuticals	<a href="#">CVMP/VICH/393388/06</a>	July 2009	EMEA	
Conduct of bioequivalence studies for veterinary medicinal products - Rev. 1	<a href="#">EMA/CVMP/016/00</a>	July 2001	EMEA	Revision: Conduct
of bioequivalence studies for veterinary medicinal products				
Conduct of pharmacokinetic studies in target animal species	<a href="#">EMA/CVMP/133/99</a>	September 2000	EMEA	

### Specific Guidelines

Název	Číslo	Datum platnosti	Zdroj	Poznám
Dossier requirements for anticancer medicinal products for dogs and cats	<a href="#">EMA/CVMP/28510/08</a>	November 2009	EMEA	

## Part IV Pre-Clinical and Clinical Trial

Written by Eva Vernerová - Last Updated Thursday, 02 March 2017 10:19

---

Conduct of efficacy studies

for non-steroidal anti-inflammatory

drugs

[7AE15a Volume 7](#) June 2002

EMEA

Efficacy of veterinary medicinal

products for use in farmed

aquatic species

[7AE22a Volume 7](#) September 1994

EMEA

Revision: Ef

medicinal products for use

in farmed aquatic species

Anticoccidials for the therapy

of coccidiosis in chickens, turkeys

and geese

[7AE15a Volume 7](#) May 1993

EMEA

Veterinary medicinal products

for zootechnical purposes

[7AE7a Volume 7](#) September 1992

EMEA

Veterinary medicinal products

for fluid therapy in case of diarrhoea

[7AE14a Volume 7](#) September 1992

EMEA

Veterinary medicinal products

controlling

*Varroa jacobsoni*

and

*Acarapis*

*Woodi*

parasitosis in bees

[7AE16a Volume 7](#)

March 1992

EMEA

products controlling

*Varroa*

*jacobsoni*

and

*Acarapis*

*Woodi*

parasitosis in bees

Performance enhancers [7AE6a Volume 7](#) November 1991

### Antimicrobials

Název

Číslo

Datum platnosti

Zdroj

Poznám

SPC for antimicrobial products

[EMEA/CVMP/SAGAM/383441/2005](#) May 2008

EMEA

Demonstration of efficacy

for veterinary medicinal products

containing antimicrobial substances

[EMEA/CVMP/627/01](#) June 2003

EMEA

**Product for intramammary use**

Název

Číslo

Datum platnosti

Zdroj

Poznám

Conduct of efficacy studies

for intramammary products

for use in cattle

[EMEA/CVMP/344/99](#)

[-Rev.1](#) September 2000

EMEA

Local tolerance of intramammary

preparations in cows [7AE21a Volume 7](#) May 1993

EMEA

### Anthelmintics

## Part IV Pre-Clinical and Clinical Trial

Written by Eva Vernerová - Last Updated Thursday, 02 March 2017 10:19

---

Název	Číslo	Datum platnosti	Zdroj	Poznámka
SPC of anthelmintics <a href="#">/2005</a> February 2008	<a href="#">CVMP/EWP/170208</a> EMA			
VICH GL7: Efficacy of anthelmintics: General requirements	<a href="#">CVMP/VICH/832/99</a>	December 2000	EMA	
VICH GL12: Efficacy of anthelmintics: Specific recommendations for equines	<a href="#">CVMP/VICH/839/99</a>	December 2000	EMA	
VICH GL13: Efficacy of anthelmintics: Specific requirements for equines	<a href="#">CVMP/VICH/840/99</a>	December 2000	EMA	
VICH GL14: Efficacy of anthelmintics: Specific requirements for caprine	<a href="#">CVMP/VICH/841/99</a>	December 2000	EMA	
VICH GL15: Efficacy of anthelmintics: Specific recommendations for equines	<a href="#">CVMP/VICH/833/99</a>	July 2002	EMA	
VICH GL16: Efficacy of anthelmintics: Specific requirements for porcines	<a href="#">CVMP/VICH/834/99</a>	July 2002	EMA	
VICH GL19: Efficacy of anthelmintics: Specific recommendations for caprines	<a href="#">CVMP/VICH/835/99</a>	July 2002	EMA	
VICH GL20: Efficacy of anthelmintics: Specific recommendations for porcine	<a href="#">CVMP/VICH/845/99</a>	July 2002	EMA	
VICH GL21: Efficacy of anthelmintics: Specific recommendations for poultry	<a href="#">CVMP/VICH/846/99</a>	July 2002	EMA	

### □ Ectoparasiticides

Název	Číslo	Datum platnosti	Zdroj	Poznámka
Revision: Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations' in dogs and cats	<a href="#">EMA/CVMP/005/00</a> EMA			
<a href="#">-Rev 2</a> June 2008				
Specific Efficacy Requirements for Ectoparasiticides in cattle	<a href="#">EMA/CVMP/625/03</a>	January 2005	EMA	
Specific Efficacy Requirements for Ectoparasiticides in Sheep	<a href="#">EMA/CVMP/411/01</a>			
January 2003	EMA			
Demonstration of efficacy of ectoparasiticides	<a href="#">7AE17a Volume 7</a>	September 1994	EMA	

### Summary of Product Characteristics (SPC)

Název	Číslo	Datum platnosti	Zdroj	Poznámka
Summary of Product Characteristics for Pharmaceutical Veterinary Medicinal Products	<a href="#">DG ENTR/F/2/KK</a>			

[D\(2006\)](#) July 2007 Eudralex  
 SPC of anthelmintics [CVMP/EWP/170208](#)  
[/2005](#) February 2008 EMEA  
 SPC for antimicrobial products [EMEA/CVMP/SAGAM/383441/2005](#) May 2008 EMEA  
 Reflection paper on the use of fluoroquinolones in food producing animals - Precautions for use in the SPC regarding prudent use guidance [EMEA/CVMP/416168/2006-FINAL](#) November 2006 EMEA

**Availability (minor use/ minor species)**

Název Číslo Datum platnosti Zdroj Poznámka  
 Efficacy and target animal safety data requirements for veterinary medicinal products intended for minor uses or minor species [EMEA/CVMP/EWP/117899/2004](#) February 2007 EMEA  
 CVMP Guidelines on Data Requirements for Veterinary Medicinal Products intended for Minor Uses on ~~Minor Species~~ [EMEA/CVMP/16672/2005-Rev.1](#) February 2007 EMEA

▣ **Multidisciplinary Guidelines**

Název Číslo Datum platnosti Zdroj Poznámka  
 CVMP Advisory Notice to Veterinary Surgeons regarding the development of fibrosarcoma at sites of injection of Veterinary Medicinal Products in cats [EMEA/CVMP/205/03](#) July 2003 EMEA  
 Fixed combination products [EMEA/CVMP/83804/05](#) July 2007 EMEA  
 Investigation of chiral active substances [EMEA/CVMP/28/95](#) January 1998 EMEA