EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

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NOTICE TO APPLICANTS
VETERINARY MEDICINAL PRODUCTS

VOLUME 6A

CHAPTER 7

GENERAL INFORMATION

July 2009

This updated chapter will be included in The Rules Governing Medicinal Products in the European Community - Notice to Applicants Volume 6A

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CHAPTER 7 GENERAL INFORMATION

Revision December 2008

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CHAPTER 7 GENERAL INFORMATION

1. FORMAT FOR APPLICATIONS IN THE E.U.

Marketing Authorisation applications, which are to be submitted in either a national or Community procedure (i.e. to competent authorities of the Member States and the European Medicines Agency (EMEA), consist of administrative information and the necessary documentation to demonstrate the quality, safety and efficacy of the veterinary medicinal product. This applies to non-immunological and immunological veterinary medicinal products.

This is presented in:

- Part I – Summary of the dossier
- Part II – Chemical/pharmaceutical/biological documentation
- Part III –Safety and residues documentation
- Part IV – Preclinical and clinical documentation

Part I: Summary of the Dossier consists of:

IA Administrative information including Marketing Authorisation particulars, proof of payment, documents on manufacturers' authorisation & samples

IB1 Proposal for the Summary of Product Characteristics (SPC)

IB2 Proposals for Packaging, Labelling & Package Insert

IB3 SPCs already approved in the Member States, as appropriate

IC Detailed and critical summaries on chemical/pharmaceutical, safety and residues and clinical documentation

Further information on the presentation and content of the dossier is given in Volume 6B of "*The Rules governing medicinal products in the European Union*".

2. LANGUAGES TO BE USED FOR DOSSIER, RESPONSES, VARIATIONS AND RENEWALS

2.1 National, Decentralised and Mutual Recognition applications (Key: / = or & = and)

Dossier	AT	BE	BG	CY	CZ	DE	DK	EE	EL	FI	FR	HU	IE	IT	LV	LT	LU
Part IA – Format	DE/EN	FR/NL/EN	BU&EN	EL/EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN[3]	LV/EN	LT/EN	FR/DE/EN
Part IB – SPC	DE/EN[23]	FR/NL/[1]EN	BU&EN	EL/EN	CZ/EN[13]	DE/EN[22]	DK/EN[2]	EE&EN	EL	FI	FR & EN	HU/EN[14]	EN	IT&EN	LV	LT&EN	FR/DE/EN
Part IB – Package insert & Labels	DE/EN[23]	FR/NL[1]	BU&EN	EL	CZ/EN[13]	DE/EN[22]	DK/EN[2]	EE&EN	EL	FI & SE	FR & EN	HU/EN[14]	EN	IT&EN	LV	LT&EN	FR/DE/LU
Part IC – Expert reports	DE/EN	FR/NL/EN	BU/EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT&EN[4]	EN	LT/EN	FR/DE/EN
Part II	DE/EN	FR/NL/EN	BU/EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN	EN	LT/EN/DE/RU	FR/DE/EN
Part III	DE/EN	FR/NL/EN	BU/EN	EN	CZ/ENSK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN	EN	LT/EN/DE/RU	FR/DE/EN
Part IV	DE/EN	FR/NL/EN	BU/EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN	EN	LT/EN/DE/RU	FR/DE/EN
Written responses	DE/EN	FR/NL/EN	BU/EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN[3]	EN	LT/EN	FR/DE/EN
Variations																	
Application form	DE/EN	FR/NL/EN	BU&EN	EN	CZ/EN	DE/EN	DK/EN	EE/EN	EL	FI/SE/EN	FR/EN	HU/EN[14]	EN	IT/EN[3]	EN	LT/EN	FR/DE/EN
Type I A/B – Documentation	DE/EN	FR/NL/EN	BU/EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN	EN	LT/EN/DE/RU	FR/DE/EN
Type II – Documentation	DE/EN	FR/NL/EN	BU/EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN	EN	LT/EN/DE/RU	FR/DE/EN
Written responses	DE/EN	FR/NL/EN	BU/EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN[3]	EN	LT/EN	FR/DE/EN
Renewal	DE/EN	FR/NL/EN	BU&EN	EN	CZ/EN/SK	DE/EN	DK/EN	EE/EN	EL/EN	FI/SE/EN	FR/EN	HU/EN	EN	IT/EN[3]	EN	LT/EN/DE/RU	FR/DE/EN

Dossier	NL	MT	PL	PT	ES	RO	SE	SI	SK	UK	EMEA	EFTA	
												NO	IS
Part IA – Format	NL/EN/DE		PL/EN	PT&EN	ES[6]& EN[16]	R0/EN	SE/EN	SI/EN[21]	SK/EN/CZ	EN	EN[8]	NO/EN	IS/EN
Part IB – SPC	NL		PL	EN/PT[10]	ES[6]/ EN	RO/EN	SE/ EN[1]	SI/EN[21]	SK/EN[15]	EN[18]	All[8]	NO/EN	IS/EN
Part IB – Package insert & Labels	NL		PL	EN/PT[10]	ES[6]/ EN	RO/EN[19]	SE/ EN[1]	SI/EN[21]	SK/EN[15]	EN	All[8]	NO/EN	IS/EN
Part IC – Expert reports	NL/EN/DE		PL/EN	EN/PT[5]	ES[6]& EN[17]	RO/EN[19]	SE/EN[12]	SI/EN	SK/EN/CZ	EN	EN[8]	NO/EN	IS/EN
Part II	NL/EN/DE		PL/EN	PT/EN[10]	ES[6]/EN	RO/EN	SE/EN	SI/EN	SK/EN/CZ	EN	EN[8]	NO/EN	IS/EN
Part III	NL/EN/DE		PL/EN	PT/EN[10]	ES/EN[7]	RO/EN[20]	SE/EN	SI/EN	SK/EN/CZ	EN	EN[8]	NO/EN	IS/EN
Part IV	NL/EN/DE		PL/EN	PT/EN[10]	ES/EN[7]	RO/EN[20]	SE/EN	SI/EN	SK/EN/CZ	EN	EN[8]	NO/EN	IS/EN
Written responses	NL/EN/DE		PL/EN	PT/EN[10]	ES/EN	RO/EN	SE/EN	SI/EN[21]	SK/EN/CZ	EN	EN[8]	NO/EN	IS/EN
Variations													
Application form	NL/EN/DE		PL/EN	PT&EN[10]	ES[6]& EN[16]	RO&EN[2]	SE/EN	SI/EN [21]	SK/EN	EN	EN[8]	NO/EN	IS/EN
Type I A/B – Documentation	NL/EN/DE		PL/EN	PT/EN[10]	ES[6]/EN	RO/EN	SE/EN	SI/EN	SK/EN/CZ	EN	–	NO/EN	IS/EN
Type II – Documentation	NL/EN/DE		PL/EN	PT/EN [10]	ES[6]/EN	RO/EN	SE/EN	SI/EN	SK/EN/CZ	EN	–	NO/EN	IS/EN
Written responses	NL/EN/DE		PL/EN	PT/EN	ES[6]/EN	RO/EN	SE/EN	SI/EN[21]	SK/EN/CZ	EN	–	NO/EN	IS/EN
Renewal	NL/EN/DE		PL/EN	PT/EN	ES[6]/EN	RO/EN	SE/EN	SI/EN[21]	SK/EN/CZ	EN	EN[8]	NO/EN	IS/EN

Notes:

1. For MRP & DCP, the SPC, labelling and leaflet should also be made available in English.
2. EN for MRP/DCP and DA for national procedures. An electronic version (QRD template) is also required.
3. EN for MRP and IT for national procedures.
4. The expert reports should be bound in separate volumes (part II, III and IV).
5. Expert Reports EN. Portuguese translation (excluding annexes) should be provided within 7 calendar days of any request by the authorities.
6. For national applications, only Spanish version can be accepted.

7. For national applications, English is acceptable if a Spanish abstract of all studies and conclusions is included.
8. Applicable only in case of a referral.
   A notification to the EMEA is required for all mututal recognition procedures containing the information listed in Chapter 2 of the Notice to Applicants Volume 6A, paragraph 2.3.6.
9. deleted
10. For national applications, only the Portuguese version is mandatory. For MRP/DCP applications, English version or English and Portuguese versions are accepted.
11. EN for MRP/DCP and SE for national procedures. An electronic version (EMEA template) is also required.
12. An electronic copy, preferably in word format, is also requested.
13. EN for MRP/DCP and CZ for national procedures. An electronic version (EMEA template) is also required.
14. EN for MRP/DCP and HU for national procedures. An electronic version (EMEA template) is also required
15. EN for MRP/DCP and SK for national procedures. An electronic version (EMEA) template) is also required.
16……..EN & ES versions are mandatory for MRP and DCP
17……..EN version is mandatory and ES version optional for MRP and DCP
18. For MRP/DCP an electronic version of the SPC and packaging should be submitted in the format of the QRD template.
19. For national applications, only the Romanian version is mandatory. For Mutual Recognition applications, English version or English and Romanian versions are acceptable.= 15
20. . For national applications, English is acceptable if a Romanian abstract of all studies and conclusions is included.
21. EN for MRP/DCP and SI for national procedures. An electronic version (EMEA template) is also required.
22. EN is sufficient for MRP/DCP in the beginning of the procedures
23 EN for MRP and DCP, DE for national procedures
24 MRP/DCP: EN until end of procedure and NO for final MA. National: NO. An additional electronic version is required

2.2 Centralised procedure applications

Dossier	**EMEA**[1]
Part IA – Format	EN
Part IB – SPC	EN
Part IB – Package Insert & Labels	EN
Part IC	EN
Part II	EN
Part III	EN
Part IV	EN
Written responses	EN
Variations	EN All[2] for SPC/PI/LAB
Application form	EN All[2] for SPC/PI/LAB
Type I –documentation	EN All[2] for SPC/PI/LAB
Type II –documentation	EN All[2] for SPC/PI/LAB
Written responses	EN All[2] for SPC/PI/LAB
Renewals	EN All[2]for SPC/PI/LAB

1. Applications for marketing authorisation have to be submitted to the EFTA countries Iceland, Norway and Liechtenstein and followed up accordingly.
2. One copy in all EU official languages and Norwegian and Icelandic for the SPCs, Labels, and Package Insert

3. NUMBER OF COPIES OF THE DOSSIER, RESPONSES, VARIATIONS AND RENEWALS

3.1 National, Decentralised and Mutual Recognition Procedures

	AT	BE[1]	BG	CY	CZ	DE	DK[25]	EE	EL	ES	FI	FR	HU	IE	IT	LV	LT	LU
Full dossier	1	1	2[44]	1	2[32]	3[8,19]	1	1[34]	1	3	1[38]	2[3]	1	1	1[29]	1	1	1[11]
Additional: Part IA	1	2	1[37]	1	1	1	1[16]		2	4[17]	1	20[3*]	1	2[47]	1[29]	1		1
Additional : IB SPC, package insert, etc.	1[24]	2	2[42]	1	0[33]		1[16]	0[35]	2	4[17]	1	20[3*]	0[33]	2[47]	2[29]	1	0[35]	
Additional: IC Expert rep.	1	2	0	0			2[16]		2	4[17]	1	20[3*]	-	2[47]	1[29,30]	1		
Additional: Part II		1	0	0						~~1~~	-		-		1[29]	1		
Biological/Biotech.		1	0	0		3					-		-	1[4]	1[29]	1		
Additional: Part III	0	0	0	0							0[1]		-		1[29]	1		
Additional: Part IV	0	0	0	0							0[1]	1[4]	-		1[29]	1		
Written responses	1	2[2]	1[37]	1	1	4	2		2	3	1[20]	2[5]	1[37]	1	2[10]	1	1	1[12]
Variations																		
Application form	1	2	1[37]	1	2	3	1	1	2	3	2	1[6]	1[37]	1	2[29]	1	1	
Type I – documentation	1	2	1	1	2	3	1[41]	1	1	3	1	1	1	1	2[29]	1	1	
Type II – documentation	1	2	1	1	2	3	1[41]	1	1	3	1	2[5]	1	1	1[29]	1	1	
Supplementary info	1	2	1	1	1	3	1	1	1	3	1		1	1	1	1	1	
Additional SPC/Package insert	1	2	2[42]	0	0[33]	3		0[35]		1[17]	1		0[33]		1[29]	1		
Additional Labels	1	2	2[42]	0	0[33]	3		0[35]		1[17]	1		0[33]		1[29]	1		
Additional statement on qualitative and quantitative composition	1		0	1		3					-				1	1		

NUMBER OF COPIES OF THE DOSSIER, RESPONSES, VARIATIONS AND RENEWALS
National, Decentralised and Mutual Recognition Procedures - Continuation

	MT	NL	PL		PT			RO	SE	SI	SK	UK	EMEA	EFTA NO / IS	
			PHARM	IMMUN											
Full dossier		1[21]	3[32]	2[32]		3[26]		2[32]	1	1	1	3[39]	23	1	1
Additional: Part IA		1	1	1		1[26]		1	1[18]		1	2[46]			
Additional : IB SPC, package insert, etc.		1[21a]	1	1		1[26]		1[33]	1[18]	0[33]	0[33]	2[46]			
Additional: IC Expert rep.		1				-			1[18]	1		2[46]			
Additional: Part II						-				1[43]					
Biological/Biotech.						-									
Additional: Part III						-			1[18]						
Additional: Part IV						-									
Written responses		1[21]				1[26]		1[37]	1[37]		1	2[40]		1[2]	1
Variations															
Application form		2[21]	2	2		2[26]		1[37]	1	1	1	15		1	1
Type I – documentation		1[45]	2[32]	2[32]		1[26]		1	1	1	1	2		1	1
Type II – documentation		1[21]	2[32]	2[32]		2[26]		1	1	1	1	3		1	1
Supplementary info		1[45]	1	1		1[26]		1	1	1	1				
Additional SPC/Package insert		1[21]; 21a	0[33]	0[33]		1[26]		0[33]	2	0[33]	0[33]				
Additional Labels			0[33]	0[33]		1[26]		0[33]	2	0[33]	0[33]				
Additional statement on qualitative and quantitative composition						- -									

Notes:

1. In Belgium, for MR/DC Procedures, we prefer receiving an electronic copy (not compulsory). When we receive an electronic copy (1 copy suffices), no paper copies have to be sent, except for a signed accompanying letter.
2. The written response should be bound in separate volumes so that the pharmaceutical assessor can review the response to Parts I and II, the pre-clinical assessor the response to Part I and Part III and the clinical assessor the response to Part I and IV
3. 3 full dossiers for immunologicals and one extra copy per species in multispecies vaccines

3 * the 20 additional copies should be provided on CD-ROMs instead of on paper

4. For pharmaceuticals
5. 1 extra copy for pharmaceuticals if the response concerns the Part III or IV. 1 extra copy for immunologicals and one extra per species in multi-species vaccines
6. 2 for immunologicals
7. 2 for immunologicals Type II and one extra copy for species in multi species vaccines
8. For vaccines for foot and mouth disease, cholera and exotic diseases a copy of the dossier should be sent to Friedrich-Löffler-Institut (FLI) Insel Riems, for all other vaccines to Paul-Ehrlich-Institute
9. deleted (December 2005)
10. For immunological products, 1 additional copy should be provided to the Istituto Superiore di Sanita
11. Only Part I (Applic./SPC/Package Insert of the originating Member State)
12. Only response relating to Part I
13. deleted (May 2008)
14. deleted (December 2005)
15. UK: Except for Mutual Recognition Type I A and 1B variation applications, when only 2 copies are required
16. An additional CD-rom version of the full dossier is also required
17. Only for MRP and DCP applications. Spanish translations of part IB can be sent from day 82 for MRP and day 202 for DCP. An electronic copy and colour mock-ups at end of procedure
18. Only for veterinary medicinal products for use in food-producing animal species
19. Pharmaceuticals: For applications for marketing authorisation using MRP/DCP: an electronic version of the SPC (.rtf format) to be sent to: mrp@bvl.bund.de (Subject: <ENR> <EU Procedure number><Name>; for renewals, variations and national applications: Submission according to AMG Submission Ordinance (AMG-EV) (information available on the website of the Federal Office for Consumer Protection and Food Safety/ Tierarzneimittel ; Explanatory Notes on the Enforcement of the Ordinance on the Submission of Documents within Licensing and Renewal Procedures for Medicinal Products (AMG-Einreichungsverordnung – AMG-EV)
20. The written response should be bound in separate volumes so that the pharmaceutical assessor can review the response to Part I and II, the pre-clinical assessor the response to Part I and III and the clinical assessor the response to Part I and IV
21. For detailed information, consult the Dutch website: www.cbg-meb.nl. Dossiers and written responses preferably submitted in an electronic format (to ensure smooth processing). Further, a covering letter is compulsory for all submissions (different applications or items in seperate letters). Please include the proposed product type, the case number (as soon as it is known) and your e-mail address. In addition a hard copy of the original signed application form is requested.

21a Part IB –one additional electronic version (in Word-format) should be submitted and sent to the e-mail address: infobd@cbg-meb.nl.

22. deleted (July 2007)
23. Applicable only in case of a referral. For information on the number of copies see paragraph 3.4.
    A notification to the EMEA is required for all mututal recognition procedures containing the information listed in Chapter 2 of the Notice to Applicants Volume 6A, paragraph 2.3.6.
24. Full dossier preferred in CD-ROM Format,
25. Subsequent correspondence during national and DCP/MRP submitted electronically are to be sent to GOD-afdelingspostkasse@dkma.dk
26. PT– All full dossier copies should be sent in CD-rom/DVD format. In case it is not possible, only one paper copy of the original dossier and separate CD-rom/DVD versions for all additional “full dossier” copies .At the end of the procedures electronic versions (preferably by e-mail) of SPC+labelling+ Mock-ups in Portugues should be submitted. Written responses should be sent by e-mail.
27. Part IB –An electronic version should be submitted at the end of the procedure.
28. on CD-ROM version

29. one copy on paper and one copy on CD-ROM version. For immunological products, 1additional copy on paper should be provided to the Istituto Superiore di Sanità
30. the expert reports should be bound in separate volumes
31. May be submitted on CD-ROM instead of paper
32. One copy of the dossier can be submitted in electronic format (CD-ROM). In the case that both copies are submitted on paper one additional copy of Part IA should be provided on CD-ROM version
33. SPC, package insert and labels should be submitted both in paper copy and in electronic format.
34. Part III and IV can be provided on CD-ROM. Paper copy should be available on request.
35. SPC, package inserts and labels (mock-ups) in the national language (Estonian and Lithuanian, respectively) should be submitted in electronic format.
36. deleted
37. An electronic copy, preferably in word format, is also requested
38. FI: Paper copies of full dossier + 2 copies on CD-ROMs at least of Part I. Electronic versions preferable in editable format.
39. UK: Except for the following applications: Marketing Authorisation Parallel Import (MAPI) applications, when only 2 copies of the full data package are required, and MR/DC procedures (new, variation and renewal) where the UK is CMS, when only 2 copies of the full data package are required, including the expert report and an optional supply of a CD in line with IFAH standards.
40. UK: Except for Mock-Ups where only 1 copy is required
41. An electronic version of the proposed SPC with track changes must be submitted simultaneously to GOD-afdelingspostkasse@dkma.dk
42. One copy on paper and one copy in electronic format both in English and Bulgarian language
43. Additional copies if requested should be submitted to JAZMP Ptujska 21, SI-1000 Ljubljana and should be preferably in electronic version with written declaration that the applicant will submit paper version within 7 days upon request.
44. One paper copy and one electronic copy in Bulgarian or English language
45. One copy preferably in an electronic format is requested.
46. UK: If the product is an Immunological product, only submit the 3 copies for the Full dossier as these additional copies are not required.
47. IE: Submit 2 copies for new product and renewal applications and single copies for responses and for variations.

3.2 National, Mutual Recognition and decentralised Procedures: number of copies requested for renewal

Further information on the presentation and content of renewal application is given in 'The Rules Governing Medicinal Products in the European Union, volume 6A (Notice to Applicants veterinary medicinal products) and volume 6C (Regulatory Guidelines) for application format'.

	RO*	**AT**	**BE**[23]	**BG**	**CY**	**CZ**	**DE**	**DK**	**EE**	**EL**	**ES**	**FI**	**FR**	**HU**	**IE**	**IT**	**LV**	**LT**	**LU**	**MT**	**NL**	**PL**		**PT**	**SE**	**SI**	**SK**	**UK**	**EFTA IS**	**EFTA NO**
European renewal application form	1	1	2	2[22]	1	2	3	1	1	2	3	2	2	1	2[15]	1	1	1	1		1[14]	2		3[7]	1	1	1	2	1	1
PSUR, incorporating compiled data on 5 years (4.5 years for the first renewal)	1[8]	1	2	1	1	2	3	1	1	1	3	1	2	1	2[15]	1[8]	1	2	1		2[14]	2		3[7]	1	1	1	1	1	1
Clinical expert report/statement that addresses the current risk/benefit of the product	1	1	2	1	1	2	3	1	1	1	3	1	2	1	2[15]	1	1	1	1		1[14]	2		3[7]	1	1	1	2	1	1
Current mutually recognised SPC	2[19]	1	2	2[22]	1	2	3	1[18]	1	1	3	2[15]	2	1	2[15]	1	1	1[9]	1		1[14]	2		1[7]	1	1	2	2	1	1
Proposed SPC	1[9]	1	2	2[22]	1	2[9]	3	1[18]	1[9]	1	3	2[15]	2	1[9]	2[15]	2	1	1[9]	1		1[14]	2		1[7]	1	1[9]	1[9]	2	1	2
Commitment to take account of new studies con-sidered necessary by the expert through the variation procedure after the renewal process is complete	1	1	2	1	1	2	3	1	1	1	3	2	2	1	2[15]	1	1	1			1[14]	2		1[7]	1	1	1	2	1	1
Copy of an updated statement of compliance with the GMP from the competent authority (not older than 3 years)	1	1	2	1	1	2	2 or 3[1]	1	1		3	2	2	1	2[15]	1	1	1	1		1[14]	2		1[7]	1	1	1		1	1

* here it was not possible to insert RO in the right alphabetical order

PL and label text relevant to each member state, for national approval only	1[9]	1	2	1[9]	1	2[9]	3	1	1[9]	1	3	2[15]	2	1[9]	2[15]	2	1	1			1[14]	2	7[3]		1[7]	1	1[9]	1[9]	2	1	2
Payment of the national fee	YES[20]	YES[13]	YES	YES[21]	YES	YES	NO	YES[5]	YES[10]	YES	YES	YES[16]	YES	YES	NO	YES[10]	YES[12]	YES	NO		YES	YES	YES	YES		YES[5]	YES	YES	YES[5]	YES	YES
Ecotoxicity documentation																1														

Notes:

1. Three copies for applications concerning immunological veterinary medicinal products to the Paul-Ehrlich-Institute
5. The fee will be invoiced by the Danish Medicines Agency/Swedish Medical Products Agency/ Veterinary Medicines Directorate
7. PT– All complete copies should be sent in CD-rom/DVD format. In case it is not possible only one paper copy of the original dossier and separate CD-rom/DVD versions for all additional copies. Electronic versions (preferably by e-mail) of SPC+labelling+ Mock-ups in Portuguese should be submitted at the end of the procedures.
8. an additional copy on CD-rom
9. SPC, Package insert and labels should additionally be submitted in electronic format.
10. State fee has to be paid prior to the submission of application, assessment fee as per invoice of the State Agency of Medicines.
11. deleted
12. Two copies of proof of payment.
13. Only if prepayment is requested (See 8. Addresses for receipt of fees and terms for payment)
14. A covering letter is compulsory for all submissions (different applications and items in seperate letters). Please include the proposed product type, the case number (as soon as it is known) and your e-mail address. Part IB –one additional electronic version (in Word-format) should be sent to the e-mail address: infobd@cbg-meb.nl..
    In case of the PSUR: one paper copy and one electronic version are requested. With regard to all other information: all official signed papers should be submitted in hard copy; an additional copy in electronic format is appreciated.
15. In addition of paper copies, 2 copies on CD-ROMs, preferable in editable format.
16. Only when FI is the RMS
17. IE: For immunological products, only 1 copy of the complete application is required.
18. An electronic version of the current and proposed SPC, PL and labelling texts is also required (e.g. CD-rom)
19. One copy in Romanian and one in English (for National Procedure – Romanian only)
20. State fee has to be paid prior to the submission of application, assessment fee as per invoice of the Institute for Control of Biological Products and Veterinary Medicines (Romania)
21. The proof of payment must accompany the application form
22. One paper copy and one electronic copy both in Bulgarian and English language
23. In Belgium, for MR/DC Procedures, we prefer receiving an electronic copy (not compulsory). When we receive an electronic copy (1 copy suffices), no paper copies have to be sent, except for a signed accompanying letter.

3.3 Applications in the Centralised procedure:

	EMEA
Full dossier [1]:	1 copy for the EMEA, plus 2 copies of Part I of the dossier (The part IB should additionally be submitted in electronic format to EMEA; 2 copies for the Rapporteur[2], 2 copies for the Co-Rapporteur[2]
Full or partial copy of the dossier	As requested by the CVMP members[3] (see "EMEA Pre-Submission Guidance for users of the Centralised Procedure" on the EMEA Website and SOP on submission of an application for the granting of a community Marketing Authorisation (SOP-V-4013)
Additional copies of Part 1	2 copies for the EMEA+ 1 electronic copy (WORD), 1 copy for the Chairman of the CVMP[3]
Written responses to questions from CVMP	2 copies for the EMEA+ 1 electronic copy of revised SPC, PIL, LAB,, 2copies for the Rapporteur[2], 2 copies for the Co-Rapporteur[2], 1 copy for the Chairman of the CVMP, 1 copy for each of the other members of the CVMP and Alternates[3]
Variation Applications[4]	
Application form	2 copies for the EMEA, 1 for the Rapporteur, 1 copy for each CVMP member[5]
Supportive documentation as appropriate: Part I	2 copies for the EMEA + electronic version, 1 for the Rapporteur, 1 copy for each CVMP member[5]
Part II-III-IV	2 copies for the EMEA, 1 for the Rapporteur, 1 copy for each CVMP member[5]

1. Whenever a full dossier is to be provided, the complete EDMF (European Drug Master File) should be included.
2. Maximum figures. If in individual situations (e.g. multiples applications) there is any divergence from the standard requirement the EMEA will inform the applicant accordingly.
3. The SOP provides the CVMP's dossier requirements, including the number of copies required of the applicants answers to questions (at "Day 121").
4. For variations that do not affect the annexes to the Community Marketing Authorisation. The Icelandic/Norwegian authorities will implicitly approve decisions on such variations. See "Guidance document for industry with regards to the extension of centralised procedures, referral procedures, parallel distribution/import and pharmacovigilance requirements to Iceland and Norway" on the EMEA website.
5. Only for Type II variations.

3.4 Applications in the Centralised procedure (renewal):

Renewal	EMEA	Rapp Co-Rapp	Other CVMP members
1. European renewal application form	**2 copies**	**2 copies**	**1 copy**
2. Appendices including:	**2 copies**	**2 copies**	**1 copy**
List of presentations in tabular format (following the template of Module 2 of the EPAR (all authorised presentations)	2 copies	2 copies	1 copy
Updated details on contact persons	2 copies	2 copies	1 copy
List of EU Member States / Norway / Iceland where the product is on the market and indicating for each country which presentations are marketed and the launch date	2 copies	2 copies	1 copy
Chronological list of Follow-up measures and Specific Obligations submitted since the granting of the MA or last renewal indicating scope, status, date of submission and date when issue has been resolved	2 copies	2 copies	1 copy
Revised list of all remaining Follow-up measures and Specific Obligations and signed letter of commitment for all outstanding commitments.	2 copies	2 copies	1 copy
Proof of payment of fee	2 copies	-	-
Quality expert statement.	2 copies	2 copies	1 copy
Currently authorised specifications for the active substance and the finished product.	2 copies	2 copies	1 copy
Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)	2 copies	2 copies	1 copy
Statement on GMP compliance (from competent authority, not older than three years)	2 copies	2 copies	1 copy
List of GMP inspections carried out at all sites indicating the date, inspection team and outcome	2 copies	2 copies	1 copy
Clinical expert statement	2 copies	2 copies	1 copy
Required Periodic Safety Update Report including Human Safety Statement (i.e. data lock point of 4½ years for first renewal and 5-year PSUR for subsequent renewals).	2 copies	2 copies	1 copy
3. Proposed texts for SPC, labelling and Package Insert in 22* languages (EU, Norway and Iceland).	1 paper copy + electronic version	2 paper copies	1 copy of the relevant language and of the English language version

* EMEA requires the EN version only on submission; other languages to be submitted after adoption of the renewal Opinion

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4. DOSSIER CHECK-IN PROCEDURE

National application number:
Date of entry Date of decision

Conclusion	**file accepted O** Yes	**not accepted O** No	Language
Part I			
Application forms	O	O	[-----]
Summary of product characteristics	O	O	[-----]
Expert Report			
Quality	O	O	[-----]
Pharmacology/Toxicology	O	O	[-----]
Residues	O	O	[-----]
Clinical	O	O	[-----]
Proof that fees have been paid	O	O	
All pages present and legible	O	O	
Draft packaging	O	O	[-----]
Draft package insert in national language	O	O	
Draft SPC in national language	O	O	
Manufacturers' authorisation of finished product	O	O	[-----]
Marketing authorisation(s)	O	O	[-----]
Sample(s)	O	O	
Letter of access to the Drug Master File	O	O	
Part I acceptable	O	O	
Not acceptable for reasons			
Part II			
Chemical, Pharmaceutical and Biological documentation	O	O	[-----]
Drug Master File	O	O	[-----]
All volumes present	O	O	
All pages present and legible	O	O	
Part II acceptable	O	O	
Not acceptable for reasons			
Part III			
Safety Documentation	O	O	[-----]
All volumes present	O	O	
All pages present and legible	O	O	
Residues Documentation	O	O	[-----]
All volumes present	O	O	
All pages present and legible	O	O	
Part III acceptable	O	O	
Not acceptable for reasons			
Part IV			
Clinical Documentation	O	O	
All volumes present	O	O	
All pages present and legible	O	O	
Part IV acceptable			
Not acceptable for reasons			

Generic applications	Yes	No
Application according to Directive 2001/82/EC, Article 13		
Evidence that a reference medicinal product has been authorised within the Community in accordance with Community provisions.	O	O
Application according to Directive 2001/82/EC, Article 13 c		
Letter of consent from the holder of the authorisation of the original proprietary medicinal product for reference to		
Part II	O	O
Part III	O	O
Part IV	O	O

5. SPECIMENS AND SAMPLES

5.1 Mock-ups and specimens

In accordance with Article 12 point 2 (k) of Directive 2001/82/EC, a specimen or mock-up of the sales presentation of the veterinary medicinal product, together with the proposed package insert must be included with the application.
A "Mock-up" is a copy of the flat artwork design in full colour, providing a replica of both the outer and immediate packaging, providing a three dimensional presentation of the labelling text of the medicinal product. It is generally referred to as a "paper copy" or "computer generated version".

A "Specimen" should be interpreted as referring to a sample of the actual printed outer and inner packaging materials and package leaflet (i.e. the sales presentation).

5.1.1 National Decentralised/Mutual Recognition applications

Specimens or mock-ups of the sales presentation, together with a proposal for the package leaflet, should be submitted with the application. In the beginning of the procedures it is sufficient to provide this documentation in English only.

5.1.2 Applications in the Centralised Procedure

The EMEA is responsible for checking of mock-ups and specimens.

Requirements for the submission of mock-ups and specimens, and their subsequent review, are detailed in "The revised checking process of mock-ups and specimens of outer/immediate labelling and package leaflets in the Centralised Procedure" (http://www.emea.europa.eu/pdfs/human/regaffair/30582106en.pdf)

New marketing authorisation procedures:

At submission (Day 0):
One multi-lingual mock-up ("worst-case") (preferably in colour) of the outer and inner packaging for each pharmaceutical form, and target species (if applicable), in the smallest pack-size must be included in Part I of the application. Additionally, one English mock-up, if English is not one of the three languages in the trilingual mock-up, should also be submitted.

After adoption of the CVMP opinion (Day 210):
A reduced[1] mock-up package and package insert is recommended to be submitted by Day 260 for every country where marketing is proposed, within 6 months of the anticipated date of the Commission Decision. At this stage, the linguistic checking procedure will be finalised and the Applicant is expected to reflect the latest agreed translations, incorporating all comments made, into the mock-ups. When this recommendation is followed, the EMEA can perform the mock-up check in 30 days in parallel to the 28 day Standing Committee consultation.
Mock-ups for countries where marketing is not proposed within 6 months of the Commission Decision should be submitted on a country-by-country basis as soon as they are

[1] Mock-ups must be submitted for the smallest pack-size of each strength and pharmaceutical form, for each container type (e.g. vial) for all relevant Member States, based on the latest version of the product information, together with a commitment that all other pack-sizes will be identical -except for pack-size specific information- and that EMEA comments will also be implemented in the other pack-sizes.

ready for the EMEA's check, well in advance of any proposed launch dates in those countries. The EMEA will perform the mock-up check within 30 days.

Before launch
Once the medicinal product is authorised and in all cases before the medicinal product is placed on the market, specimens of the final outer and inner packaging and the package leaflet must be submitted for review to the EMEA within a timeframe agreed between the EMEA and the Marketing Authorisation Holder.

Variation applications:
Revised mock-ups should be included in variation applications where the variation implies changes to outer/inner label and/or package leaflet. For Type II procedures, revised mock-ups should be provided by day 20 after adoption of the opinion. Once the Variation has been approved and before launch of the amended product information, specimens of the final revised outer/immediate packaging and/or of the Package Leaflet must be submitted to the EMEA within a timeframe agreed between the EMEA and the Marketing Authorisation Holder.

5.2 Samples

Samples of the (non-) active principles and of the finished medicinal product must be supplied at the same time as the submission of the dossier as a matter of course to the competent authorities in Estonia, Hungary, Lithuania, Luxembourg, Spain and Sweden in accordance with the requirements set out in this Table. In other cases, samples should be provided at the request of the competent authorities (information is lacking for MT at present).

REQUIREMENTS FOR SAMPLES IN THE MEMBER STATES

Number of samples	AT	BE	BG	CZ	DE	EE	EL	ES	FR	HU	IT	LV	LT	LU	MT	PL	PT	R0	SE	SK	EFTA	
																					NO	IS
Finished medicinal product	F	F	A,B **	A,B, C	F	A	F	A	A	A,H	A	A,F	A,H	A		F	A,B,C	A, B, C	A*	A,B,C	F	C
All active substances	F	F	I**	B,C	F	H	F						B	A		F	B, C	F	E	B,C	F	
Non-pharmacopoeial active substances		F	F				F						F			F		F				
Non-active substances		F	F	F			F						F			F		F		F		

The appropriate number of samples should be provided:

A) in the form of final sales presentation of the medicinal product

B) in sufficient quantity to permit a full assay and the verification of the control methods used by the manufacturer.

C) Samples should be provided within 7 calendar days of any request by the authorities. They are not required to accompany the application.

D) 2 samples of the non-pharmacopoeial active and non-active substances have to be provided and in sufficient quantity to permit 2 full assays and the verification of the control methods included in Part II.

E) Reference materials, main impurities and main degradation products and non-active substances must be submitted on request.

F) Samples should be made available on request

G) On request, samples should be provided within 7 calendar days in the presentation authorised in the RMS and in sufficient quantity to permit 2 full assays and the verification of the control methods included in Part II. If a measuring device is included in the medicinal product, two samples should also be provided.

H) Reference materials, main impurities and main degradation products should be provided on request within 7 calendar days and in sufficient quantity to permit 2 full assays and the verification of the control methods used by the manufacturer.

* Placebo samples rather than drug containing samples should be submitted if the drug substance is classified as a narcotic substance or if the drug substance is cytostatic or otherwise particularly toxic.

** For the national procedure only (during the mutual recognition procedure samples should be made available on request)

I) Reference materials, main impurities and main degradation products should be provided with the application form and in sufficient quantity to permit 2 full assays and the verification of the control methods used by the manufacturer.

PROVISION OF SAMPLES OF NON-IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Number of samples	AT	BE	CZ	EE	ES	EL	FR	HU	LV	LT	LU	MT	PL	PT	SE	SK	RO
Finished product	***	1***	x	x	x	x	1**	x	1**	2	1*		x	1 X	1***	x	x
All active substances	***	1***	x	x						x			x	***		x	x
Only active substances for which the applicant has introduced a monograph																	
Non-active substances for which the applicant has introduced a monograph			x													x	

Notes

* The appropriate number of samples should be provided in the final sales presentation authorised in the Reference Member State (LU).

** One sample of each presentation of the finished product in the final sales form with the corresponding batch analysis.

*** On request, samples should be provided within 7 calendar days in the presentations authorized and in sufficient quantity to permit 2 full assays

x In other cases, the sample should be provided in sufficient quantity to permit the full assay and verification of the control methods used by the manufacturer

In the other Member States samples should be provided only upon request of the competent authorities (information is lacking for MT at present).

PROVISION OF SAMPLES OF IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Number of samples	**AT**	**BE**	**CZ**	**EE**	**ES**	**EL**	**HU**	**LV**	**LT**	**MT**	**PL**	**SE**	**SK**	**RO**
Finished product	**	1**	x	x	x	x	x	1*	x		x	1**	x	x
All active substances	**	1**	x	x					x		x		x	-
Only active substances for which the applicant has introduced a mono-graph														
Non-active substances for which the applicant has introduced a mono-graph			x										x	

Notes

* the appropriate number of samples should be provided in the final sales presentation uthorizat by the reference Member State (LV)

** on request, samples should be provided within 7 calendar days in the presentations authorized and in sufficient quantity to permit 2 full assays

x in other cases, the sample should be provided in sufficient quantity to permit the full assay and verification of the control methods used by the manufac-turer

In the other Member States samples should be provided only upon request of the competent authorities (information is lacking for MT at present).

6. NATIONAL PROCEDURE AFTER A COMMISSION DECISION ON A REFERRAL

Information on national procedures to be followed to adapt national marketing authorisations after a Commission Decision on a referral is provided below.

Austria

The Federal Agency for Safety in Health Care will request the MAH to amend the marketing authorisation by variation in accordance with the Commission Decision. The MAH should submit:

- Cover letter
- Application forms
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

The Federal Agency for Safety in Health Care will amend the marketing authorization and inform the Commission and EMEA.

Belgium

The Belgian authority will request the MAH to amend the marketing authorisation by variation in accordance with the Commission Decision. The MAH should send the following information:

- Cover letter
- Application forms
- Proof of payment of fees
- Original AMM and product literature
- Amended SPC
- Amended Package Leaflets and Labelling

The marketing authorisation will be amended and the Belgian authorithy will inform the Commission and EMEA.

Bulgaria

The Director General of the National Veterinary Service will request the marketing authorisation holder (MAH) to amend the marketing authorisation by variation in accordance with the Commission Decision. The MAH should sent the following information:

- Application forms
- Cover letter
- Proof of payment of fees
- Comprehensive product data
- Amended SPC, Package Leaflets and Labeling (highlighted and clean versions)

Czech Republic

The Institute for State Control of Veterinary Biologicals and Medicaments requests the MAH to proceed the following way for the national implementation of the Commission Decision concerning referrals:

Article 33: No variation notification required

Article 34: National Type IB 46 notification

Article 35: National Type IB 46 notification

The ISCVBM will amend the marketing authorisation and inform the Commission
and EMEA.

Denmark

The Danish Medicines Agency amends the marketing authorisation and issues a revised SPC (if relevant) according to the Commission Decision. The Danish Medicines Agency will inform EMEA and the European Commission of the date of implementation of the decision.

For products not included in the Commission Decision, the national implementation of the decision should be made with a Type IB variation application for Art. 34 referrals (IB no. 46 within 90 days of CD) and with a Type II variation application for Art. 35 referrals.

Estonia

The Estonian State Agency of Medicines asks the MAH to implement changes in the product information (SPC, package leaflet and labelling) according to the Commission Decision).

Finland The National Agency for Medicines will request the MAH to amend the marketing authorisation via a national type II variation in accordance with the Commission Decision. The MAH should send to the National Agency for Medicines the following documentation:

- Cover letter
- Application forms
- Proof of payment of fees
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

The National Agency for Medicines will amend the marketing authorisation and inform the Commission and EMEA.

France The French Agency for Veterinary Medicinal Products amends the marketing authorisation according to the Commission Decision.

Germany The German authority initiates an oral hearing according to the Graduated Plan (Stufenplan § 63) of the Medicines Act with the request to MAH to amend the marketing Authorisation in line with the Commission Decision.

- The MAH should provide the amended version of SPC, package leaflet and labelling
- The authority will issue an updated marketing authorisation and inform the Commission thereof

Hungary The Hungarian authority contacts the MAH according to Article 37(3) of the Decree 50/2006.(VI.28.) MARD on veterinary medicinal products with the request to amend the marketing Authorisation in line with the Commission Decision.

- The MAH should provide the amended version of SPC, package leaflet and labelling (highlighted and clean version)
- The authority will issue an updated marketing authorisation and inform the Commission and the Bundesländer thereof.

Italy

The Italian Ministry of Health for Veterinary Medicinal Products amends the marketing authorisation according to the Commission Decision.

The MAH should send the following documentation:

- Cover letter
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

Lithuania

The Lithuanian State Inspection on Veterinary Preparations amends the marketing authorisation according to the Commission Decision.

For medicinal products not included in the Commission Decision the national implementation of the Decision should be done via variation application - Type IB No. 46 for referral Art 34 and Type II for referral Art 35.

Poland

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products requests the MAH to amend the marketing authorisation via a national type II variation in accordance with the Commission Decision.

Within 7 days the MAH should submit to Polish Agency the following documentation:

- Application form for variation
- Marketing authorisation
- Amended version Summary of Product Characteristics
- Amended version of Package Information Leaflet and labeling (if applicable)
- Approved version Summary of Product Characteristics
- Approved version of Package Information Leaflet and labeling (if applicable)
- Power of attorney
- Proof of payment of fees

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products will amend the marketing authorisation.

Portugal **DGV**

The Portuguese authorities will request the MAH to amend the marketing authorisation in line with the Commission decision, via a national type II variation.
The MAH should send the following documentation:

- Cover letter
- Application forms
- Proof of payment of fees
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets ,Labelling (highlighted and clean versions, if applicable) and mock-ups

The DGV will amend the marketing authorisation and inform the Commission and EMEA.

Romania The Institute for Control of Biological Products and Veterinary Medicines will request the MAH to amend the marketing authorisation by variation in accordance with the Commission Decision. The MAH should submit:

- Cover letter
- Application forms
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)
- Proof of payment of fees

The marketing authorisation will be amended and the Romanian authorithy will inform the Commission and EMEA.

Slovakia

For the implementation of the Commission Decision concerning referral Art. 34 and 35 Institute for the state control of veterinary Biologicals and Medicaments starts the administrative procedure for medicinal products included in the Commission Decision asking for sending adapted summary of product characteristics, package information leaflet and labelling (if applicable) - no application for variation is needed.

For medicinal products not included in the Commission Decision the national implementation of the Decision should be done via variation application - Type IB No. 46 for referral Art 34 and Type II for referral Art 35. :

- Cover letter
- Application forms
- Proof of payment of fees
- Amended SPC (highlighted and clean version)
- Amended Package Leaflets and Labelling (highlighted and clean version, if applicable)

The marketing authorisation will be amended and the Slovakian authorithy will inform the Commission and EMEA.

For referrals Art 33, no variation application is required for the national implementation.

Slovenia

After receiving the Commission decision an applicant or marketing authorisation holder should submit promptly (within 10 days) to the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) the following documentation:

- adapted Summary of Product Characteristics (highlighted and clean versions)
- adapted Package Information Leaflets and Labelling (highlighted and clean versions) (if applicable)

Consequently the JAZMP issues an updated marketing authorisation and inform the Commission thereof.

For products not included in the Commission Decision, the national implementation of the decision is highly recommended and should be made with a Type IB, NO. 46 variation application for Art. 34 referrals and with a Type II variation application for Art. 35 referrals.

For referrals Art 33, no variation application is required for the national implementation.

Spain

The Veterinary Medicines Directorate will request the MAH to amend the marketing authorisation by variation in accordance with the Commission Decision. The MAH should submit:

- Cover letter
- Part IA
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

The VMD will amend the marketing authorisation and inform the Commission and EMEA.

Sweden

National implementation of decisions concerning referrals in Sweden

To facilitate a national implementation of the Commission decision concerning referral Art 34 and 35, the MPA requests via fax the companies to immediately submit a national Type II variation application. For products not included in the Commission decision, the national implementation of the decision should be made with a Type IB variation application for referral Art 34 (IB 46 within 90 days of the CD) and with a Type II variation application for referral Art 35.

For referrals Art 33, no variation application is required for the national implementation.

Article	**Products included in the decision**	**Products not included in the decision**
33	No variation notification required	-
34	National Type II variation (request via fax to MAH) IB 46 notification (within 90 days of the decision)	
35	National Type II variation (request via fax to MAH) Type II variation	

United Kingdom

The Veterinary Medicines Directorate will request the MAH to amend the marketing authorisation by variation in accordance with the Commission Decision. The MAH should submit:

- Cover letter
- Application forms
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

The VMD will amend the marketing authorisation and inform the Commission and EMEA.

Iceland

IMCA will request the MAH, by sending a letter or an e-mail to amend the marketing authorisation by variation in accordance with the Commission Decision. The MAH should send the following information:

-Cover letter
-Application forms
-Amended SPC (highlighted and clean versions)
-Amended Package Leaflets and Labelling if relevant (highlighted and clean versions)

Consequently IMCA sends an invoice to the MAH and updates the MA accordingly

Norway:

The Norwegian Medicines Agency amends the marketing authorisation and issues revised SPC, PL and label (if relevant) according to the Commission Decision. No application for variation is needed.

As part of the arbitration procedure a national translation of the text of the SPC is assessed in our agency when the CVMP opinion is finalised, i.e. following the QRD linguistic review procedure.
When a Commission Decision (CD) following an Article 34 or 35 is received it is adopted by the Norwegian Medicines Agency (NoMA). The NoMA receives via Eudralink the corrected Norwegian translation of the SPC, PL and label as appropriate, from the EMEA, as part of the QRD linguistic review.

MAH of products containing the same active substance(s) but not incorporated in the Article 34 or Article 35 referrals, are encouraged to submit variation applications in order to harmonise the SPC, PL and label as appropriate. The variations are considered as type IB provided that they are submitted within 90 days of the publication of the CD. Later than this deadline the variations are type II.

7. LIST OF OFFICIAL JOURNALS

The name and address of the Official Journal in each Member State (where the decisions to grant the marketing authorisation are published) is given below:

AUSTRIA	**Mitteilungen der Sanitätsverwaltung** Medieninhaber und Herausgeber: Bundesministerium für Gesundheit Familie und Jugend Sektion III / Gesundheitswesen Radetzkystr. 2 1030 Wien
BELGIUM	**Belgisch Staatsblad** Leuvensestraat 40-42 B-1000 Brussel **Moniteur Belge** Rue de Louvain 40-42 B-1000 Bruxelles
BULGARIA	Decisions and details of authorisation will be published on website: www.mzgar.government.bg/
CYPRUS	**Official Journal of Republic of Cyprus Government Office** Michalaki Karaoli str. 1445 Nicosia Tel: +35722405829, +35722405838-9 Fax: +35722303175 Website: www.cygazette.com
CZECH REPUBLIC	**Věstník ÚSKVBL** **Ústav pro státní kontrolu veterinárních biopreparátů a léčiv** Hudcova 56a 621 00 Brno – Medlánky Tel: +420 541 518 222/211 Fax: +420 541 210 026 E-mail: uskvbl@uskvbl.cz Website: www.uskvbl.cz
DENMARK	Decisions and details of authorisations are published on the **DMA website**: www.dkma.dk

ESTONIA	**Decisions will be published on website:** **www.sam.ee** **Contact:** State Agency of Medicines Nooruse 1 50411 Tartu Estonia Tel: +372 7 374 140 Fax: +372 7 374 142 e-mail: sam@sam.ee
FINLAND	**Virallinen Lehti, Officiella tidningen** Oy Edita Ab/Virallinen Lehti P.O. Box 745 FIN-00043 Edita
FRANCE	**Journal Officiel de la République Française** 26 rue Desaix F-75015 Paris
GERMANY	**Bundesanzeiger Verlags GmbH** Postfach 10 05 34 D-50445 Köln
GREECE	**Ephimeris Kyvernisseos Ellenikis Dimokratias** (Official Journal, Government Publications) Kapodistriou 34 EL-Athens
HUNGARY	**Földmüvelésügyi és Vidékfejlesztési Értesítö** H-1085 Budapest, Somogyi Béla u. 6
IRELAND	**Iris Oifigiúil**, Government Publications Sale Office Sun Alliance House Molesworth Street Dublin 2 Ireland
ITALY	**Gazzetta Ufficiale della Repubblica Italiana** Istituto Poligrafico e Zecca dello Stato Piazza G. Verdi 10 I-00198 Roma
LATVIA	**Latvijas Vēstnesis** Official Journal of the Republic of Latvia Bruņinieku street 41 RIGA, LV – 1011, LATVIA

LITHUANIA	**„Valstybės žinios“** Gedimino pr.53 01109 Vilnius-2
LUXEMBURG	**Mémorial** Service Central de Législation Boulevard F. D. Roosevelt L-2450 Luxembourg
MALTA	-
NETHERLANDS	**Nederlandse Staatscourant** Postbus 20014 NL-2500 EA Den Haag
POLAND	Official Journal of Minister of Health **Dziennik Urzędowy Ministra Zdrowia** Miodowa 15 00 – 952 Warsaw Poland
PORTUGAL	**Diario da Republica** Casa da Moeda EP Rua D. Francisco Manuel de Melo 5 P-1092 Lisboa Codex
ROMANIA	**Decisions will be published on website:** **www.icbmv.ro** **Contact:** **Institute for Control of Biological Products and Veterinary Medicines** Tel: +40212202112 Fax: +40212213171 e-mail: icbmv@icbmv.ro
SPAIN	**Boletin Oficial del Estado** Trafalgar 27 E-28010 Madrid
SWEDEN	Decisions are published on the **MPA website**: www.mpa.se
SLOVAKIA	**Vestník MP SR** **Ministerstvo pôdohospodárstva Slovenskej republiky** Dobrovičova 12 812 66 Bratislava Slovenská republika

SLOVENIA	**Uradni list Republike Slovenije** Slovenska 9 SI-1000 Ljubljana Slovenija
UNITED KINGDOM	The UK will publish details of authorisations in the Veterinary Medicines Directorate's publication, "MAVIS". This information will also be available on the VMD website address, www.vmd.gov.uk
EUROPEAN UNION	**Official Journal of the European Union** Office for Official Publications of the European Communities 2, rue Mercier L-2985 Luxemburg
EFTA	
ICELAND	**Lögbirtingablaðið** Ránarbraut 1 IS-870 Vík
NORWAY	**Norsk Lysingsblad** Njøsavegen 2 NO-6863 Leikanger Lysingsbladet@norge.no

8. ADDRESSES FOR DELIVERY OF THE DOSSIER AND SUBSEQUENT CORRESPONDENCE

Austria

Bundesamt für Sicherheit im Gesundheitswesen
Federal Agency for Safety in Health Care
Institut: LCM
Schnirchgasse 9
A-1030 Wien
Tel: +43 50 555-36670
Fax: +43 50 555-36509

Belgium NL/FR

Federal Agency for Medicines & Health Products
Eurostation block II
Place Victor Horta 40, box 40
1060 Brussels
Belgium
Tel.: 0032 2 524 80 00;
Fax.: 0032 2 524 80 01

Bulgaria

The Director General of the National Veterinary Service
(Attn: Dr.Ivayla Davidova-'Control of VMP' Department)
15 A "Pencho Slaveykov" Blvd.
1606 Sofia, Bulgaria
Tel: +35929159820 (General)/ +359 2 915 98 69
Fax:+35929549593 (General)/+359 2 915 98 69
For contacts:
J.Baichev@nvms.government.bg
i_davidova@nvms.government.bg

Cyprus

Ministry of Agriculture and Environment
Veterinary Services
1417
Nicosia

Czech Republic

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
Hudcova 56a
621 00 Brno – Medlánky
Tel: +420 541 518 222/211
Fax: +420 541 210 026
e-mail: uskvbl@uskvbl.cz
Website: www.uskvbl.cz

Denmark

Lægemiddelstyrelsen
Axel Heides Gade 1
DK – 2300 København S
Tel: +45 44 88 95 95
Fax: +45 44 88 95 99
GOD-afdelingspostkasse@dkma.dk

Estonia

State Agency of Medicines
Nooruse 1
50411 Tartu
Tel: +372 7 374 140
Fax: +372 7 374 142
e-mail: sam@sam.ee

Finland

National Agency for Medicines
Marketing Authorisations
Mannerheimintie 103 b
P.O. Box 55
FIN-00301 Helsinki
Tel : +358 9 4733 41
Fax : +358 9 4733 4355
Delivery address :
Nauvontie 4
FIN-00300 Helsinki

France

AFSSA – ANMV Agence Nationale du Médicament Vétérinaire
La Haute Marche
Javené – B.P. 90203
F-35302 Fougères
Tel: +33 2 99 94 78 82
Fax: +33 2 99 94 78 64
e-mail: enreg@anmv.afssa.fr

Germany

Non immunological veterinary medicinal products
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Abteilung 3
Mauerstraße 39-42
D-10117 Berlin
Tel: +49 30 18444-30001
Fax: +49 30 18444-30008

Immunological veterinary medicinal products
Paul Ehrlich Institut
Bundesamt für Sera und Impstoffe
Paul-Ehrlich Strasse 51-59
D-63225 Langen 1
Tel: +49 61 03 770
Fax: +49 61 03 77 1234

For vaccines for foot and mouth disease, hog cholera and exotic diseases a copy of the dossier should be sent to:
Bundesforschungsanstalt für Viruskrankheiten der Tiere Institute auf der Insel Riems (Friedrich-Löffler-Institut)
Boddenblick 5a
D-17493 Greifswald - Insel Riems
Tel: +49 38351 70
Fax: +49 38351 7 219

Greece

Evaluation Division, Section of Veterinary products
EOF
Mesogion Avenue 284
Holargos
GR-Athens 155 62
Tel: +30 210 650 72 77 or 6507278 or 6507387
Fax: +30 210 653 75 91

Hungary

Mezőgazdasági Szakigazgatási Hivatal
Állatgyógyászati Termékek Igazgatósága
(Cental Agricultural Office
Directorate of Veterinary Medicinal Products)
Address:H-1107 Budapest, Szállás u. 8
Correspondence: H-1475 Budapest 10. Pf. 318
Tel: +36 1 433 0330
Fax: +36 1 262 2839
e-mail: info.aogyti@oai.hu
Website: www.ivmp.gov.hu

Ireland

Irish Medicines Board
Receipts and Validation Department
Kevin O'Malley House
Block A, Earlsfort Centre
Earlsfort Terrace,
Dublin 2
Ireland
Tel: +353 1 676 4971
Fax: +353 1 676 7836

Italy

Immunological and non immunological veterinary medicinal products
Ministero della Salute
Direzione Generale della Sanità Animale e del Farmaco Veterinario – UFF. IV DGSA
Piazzale Marconi 25
I-00144 Roma EUR
Tel: +39 06 59 94 65 84
Fax: +39 06 59 94 69 49, 59 94 66 76 or 59 94 62 17

Immunological veterinary medicinal products
One further copy of the dossier should be submitted to:
Dipartimento di Sanità Alimentare ed Animale
Istituto Superiore di Sanità
Viale Regina Elena 299
I-00161 Roma
Tel: +39 06 49 38 70 76
Fax: +39 06 49 38 70 77

Latvia

Food and Veterinary Service,
Veterinary Medicinal Products Registration Division
Republikas laukums 2, Riga, LV-1010, LATVIA
Tel: +371 7095239
Fax: +371 7027475

Lithuania

Lithuanian State Inspection on Veterinary Preparations
J. Naujalio g. 21b, LT-48332 Kaunas-26,
LITHUANIA (Lietuva)
Tel.: +370 37 268129, 267455
Fax: +370 37 361241
http://www.lvvpi.lt

Luxemburg

Villa Louvigny
Division de la Pharmacie et des Médicaments
Allee Marconi
L – 2120 LUXEMBOURG
Tel: +352 478 55 95;
Fax: +352 26 20 01 40 or +352 26 20 01 47

Malta

-

Netherlands

College ter Beoordeling van Geneesmiddelen
Medicines Evaluation Board
Veterinary Medicinal Products Unit
2nd Floor Forum Building, Post room MEB Agency
Kalvermarkt 53
2511 CB The Hague
The Netherlands
Tel: +31 70 356 74 00
Fax: +31 70 356 75 15
Visiting address:
College ter Beoordeling van Geneesmiddelen
Medicines Evaluation Board
Veterinary Medicinal Products Unit
Haagsteeg 2
NL-6708 PM Wageningen
e-mail: infobd@cbg-meb.nl
Website: www.cbg-meb.nl

Poland

URZĄD REJESTRACJI
PRODUKTÓW LECZNICZYCH, WYROBÓW MEDYCZNYCH
I PRODUKTÓW BIOBÓJCZYCH
tel. (+48-22) 492-11-00
fax. (+48-22) 492-11-09
ul. Ząbkowska 41, 03-736 Warszawa
www.urpl.gov.pl

Portugal

DGV - Direcção Geral de Veterinária
Lg da Academia Nacional de Belas Artes 2
1294-105 Lisboa
Tel: +351 21 323 9533 **/9717**
Fax: +351 21 323 9565
http://www.dgv.min-agricultura.pt

Romania

Institute for Control of Biological Products and Veterinary Medicines
39 Dudului Street, sector 6, postale code 060603
Bucharest, Romania
Tel: +40212202112
Fax: +40212213171
e-mail: icbmv@icbmv.ro

Spain

Ministerio de Sanidad y Consumo
Agencia Española de Medicamentos y Productos Sanitarios
Parque Empresarial Las Mercedes
C/ Campezo, 1 – Edificio 8
28022 MADRID
Fax: +34 91 82 25 443

Sweden

Medical Products Agency
Registration Office
Dag Hammarskjölds väg 42
P.O. Box 26
SE-751 03 Uppsala
Tel: +46 18 17 46 00
Fax: +46 18 54 85 66

Responses that are submitted by e-mail should be addressed to the general e-mail address sok.central@mpa.se via normal e-mail or Eudralink.
A hard copy is also requested. Please indicate on both documents that they have also been sent by e-mail/as hard copy.

Slovakia

Ústav štátnej kontroly veterinárnych biopreparátov a liečiv
Biovetská 34, P.O.BOX 52/C
949 01 Nitra
Tel.: + 421 37 6933511 – 513
Fax: +421 37 6517 915
e-mail: uskvbl@uskvbl.sk
Website: www.uskvbl.sk

Slovenia

JAVNA AGENCIJA REPUBLIKE SLOVENIJE ZA ZDRAVILA IN MEDICINSKE PRIPOMOČKE
Ptujska ulica 21
SI- 1000 LJUBLJANA
Slovenija

United Kingdom

Veterinary Medicines Directorate
Information Management Section
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS
United Kingdom
Tel: +44 1932 33 84 44
Fax: +44 1932 33 66 18

EMEA

European Medicines Agency (EMEA)
7 Westferry Circus
Canary Wharf
UK-London E14 4HB
Tel: +44 207 418 84 00
Fax: +44 207 418 84 47; +44 207 418 84 16

EFTA

Iceland

Lyfjastofnun
The Icelandic Medicine Control Agency (IMCA)
Eiðistorg 13-15
IS-170 Seltjarnarnes
Iceland
Tel: +354 520 2100
Fax: +354 561 2170
e-mail: lyfjastofnun@lyfjastofnun.is or imca@imca.is

Norway

Statens legemiddelverk (Norwegian Medicines Agency)
Sven Oftedals vei 8
NO-0950 OSLO
Norway
Tel: +47 22 89 77 00
fax numbers:
Mutual Recognition matters: +47 22 89 75 21
Central Procedure matters: +47 22 89 75 54
Other matters: +47 22 89 77 99
e-mail: post@noma.no

9. ADDRESSES FOR RECEIPT OF FEES AND TERMS FOR PAYMENT

Austria

Published national rules – Gebührentarif:
Verordnung des Bundesamtes für Sicherheit im Gesundheitswesen über den Gebührentarif gemäß GESG

Available on Internet www.ages.at

Address for advice on fees
Bundesamt für Sicherheit im Gesundheitswesen
Federal Agency for Safety in Health Care
Institut: LCM
Schnirchgasse 9
A – 1030 Wien
Tel: +43 50 555-36670
Fax: +43 50 555-36509

Fees payable to:
Bank Austria-Creditanstalt
Konto Nummer: 50670 871 619
BLZ: 12000
IBAN; AT971200050670871619
BIC/SWIFT: BKAUATWW

Method of payment:
Only on postal account - please be aware that banks will charge you for transactions fees, cheques are not accepted.
The invoice number, the client number and the name of the product must be stated.
No fees should be paid in advance of the submission.

Belgium

Published national rules:
K.B. betreffende geneesmiddelen voor menselijk en diergeneeskundig gebruik
A.R. relatif au médicaments à usage humain et vétérinaire
(text available only in Dutch and French)

Available from address for advice on fees:
Federal Agency for Medicines & Health Products
Eurostation block II
Place Victor Horta 40, box 40
1060 Brussels
Belgium
Tel.: 0032 2 524 80 00
Fax.: 0032 2 524 80 01

Fees payable : A deposit should be made on the following bank account: Nr.: 679-0021942-20
Address: Financiële Post, Antwerpse steenweg 59, 1100 Brussel
Swift code: PCHQBEBB
IBAN code: BE28 6790 0219 4220

Method of payment:
Only on the postal account, in € (Euros)
Cheques are not accepted
The name of the applicant and the name of the product must be stated
Proof of payment is required before an application can be accepted

Bulgaria

The Director General of the National Veterinary Service
15 A ”Pencho Slaveykov” Blvd.
1606 Sofia, Bulgaria
Tel: +35929159820 (General)/ +359 2 915 98 69
Fax:+35929549593 (General)/ + 359 2 915 98 69

Method of payment:
Only as bank transfer to the NVS’s bank accounts; cheques are not accepted. The name of the product, its concentration and the name of the applicant should be stated. Proof of payment should accompany the application.

Fees payable to:

The NVS’s bank account in <u>BGN</u> is:

ЕИК: 121240206
ИН по ЗДДС: BG121240206
IBAN: BG37UNCR75273159861101
BIC: UNCRBGSF
"UniCredit Bulbank",
'Tzar Boris III" Branch.

The NVS’s bank account in <u>Euro</u> is:

BG12 BNBG 9661 3400 1501 40
of "Bulgarian National Bank",
by "Deutsche Bank"-Frankfurt
10092334950000, Swift code DEUTDEFF
IBAN DE 53500700100923349500.

All commissions are on the applicant's account.The VAT registration number of the applicant should be stated on the proof of payment.

Cyprus **Ministry of Agriculture and Environment**
Veterinary Services
1417
Nicosia
The receipt of fees must be supplied at the same time as the submission of the dossier.

Czech Republic

Published national rules:

Zákon č. 378/2007 Sb., o léčivech, (platný od 31.12.2007)
(Act No 378/2007 Coll., on Pharmaceuticals, (came in force 31.12.2007)

Zákon č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů
(Act No 634/2004 Coll., on Administrative fees, as last amended)

Available from:

Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
Hudcova 56a
621 00 Brno - Medlánky
Czech Republic
Tel: +420 541 518 222/211
Fax:+420 541 210 026
E-mail:uskvbl@uskvbl.cz

Website:

Czech version of the instruction for applicants concerning payment particulars:
www.uskvbl.cz / Správní poplatky, úhrada nákladů / UST 01 2006 / USKVBL-UST-1-2006 - Správní poplatky a úhrady nákladů za odborné úkony prováděné na žádost
English version of the instruction for applicants concerning payment particulars:
www.uskvbl.cz / Správní poplatky, úhrada nákladů /UST 01 2006 en / USKVBL-UST-1-2006 - Administrative fees and payments of costs of expert tasks performed on request

Method of payment and bank details:

Payments must be made in advance of the application submission. A proof of payment must accompany the application.

Two kinds of the fee:

1.Administrative fees: A fee stamp (according to the instruction for applicants concerning payment particulars USKVBL/UST-1/2006) or a bank transfer

Bank name: ČESKÁ NÁRODNÍ BANKA (ČNB)
Bank address: Rooseveltova 18, 631 32 Brno, Czech Republic
Account number: 3711-31229641/0710
Payment title: 355 – Výzkum a vývoj
Constant symbol: 1148
SWIFT code: CNBACZPP
IBAN code: CZ17 0710 0037 1100 3122 9641

2.Payments of costs: Bank transfer

Bank name: ČESKÁ NÁRODNÍ BANKA (ČNB)
Bank address: Rooseveltova 18, 631 32 Brno, Czech Republic
Account number: 35-31229641/0710
Payment title: 355 – Výzkum a vývoj
Constant symbol: 1148
SWIFT code: CNBACZPP
IBAN code: CZ76 0710 0000 3500 3122 9641

Denmark

Published national rules:
Indenrigs- og Sundhedsministeriets bekendtgørelse nr. 1416 af 13.12.2006 om afgifter for lægemidler og fremstillere af lægemidler, mellemprodukter og råvarer.

Available from address for advice on fees:
Lægemiddelstyrelsen
Axel Heides gade 1
DK-2300 København S
Tel: +45 44 88 95 95
Website: www.dkma.dk

Fees payable to:
Lægemiddelstyrelsen
Axel Heides gade 1
DK-2300 København S
Tel: +45 44 88 95 95
The fee will be invoiced by the Danish Medicines Agency

Method of payment:
Postal cheque service 9 18 4295
From other EC countries:
Jyske Bank
Vesterbrogade 9
DK-1780 København V, Danmark
reg. no. 8109
account no. 100835-9
or
reg.no. 5010
account no. 122275-5
S.W.I.F.T./BIC code: JYBADKKK

Estonia

State Fee payable to:
Ministry of Finance (Rahandusministeerium)
Account no: 221023778606
IBAN: EE932200221023778606
SWIFT code: HABA EE2X
Pank: HANSAPANK
Address: Liivalaia 8, Tallinn 15040, ESTONIA

Reference number: 2900073520

Method of payment:
The name of the product and the reference number must be stated.
The state fee has to be paid prior the submission of the application.
Proof of payment of the state fee should be enclosed to the application.
The proof of payment should include at least the following data:
the name of the product, pharmaceutical form and strength;
the number and type of applications;
reference number as follows: 2900073520

Assessment fee payable to:
Rahandusministeerium
1 Suur-Ameerika Str., 15006 Tallinn, Estonia
Beneficiary's bank: Hansapank, Liivalaia 8, 15040 Tallinn, Estonia
Account number: 221013921094
IBAN: EE492200221013921094
SWIFT/BIC code: HABAEE2X
Through: Deutsche Bank, Frankfurt
SWIFT/BIC code: DEUTDEFF
reference number 2100010891

Reference number and invoice number must be stated.

Method of payment:
An invoice will be sent upon receipt of the application. No payment should be made in advance.
Please make sure that the whole amount of the will be credited to our account net of any charges from the issuing or receiving bank.

Finland

Published national rules:
Decision of the Ministry of Social Affairs and Health concerning activities of the National Agency for Medicines subject to fees

Available in internet www.nam.fi **and also from:**
National Agency for Medicines
Department of General Affairs
Mannerheimintie 103 b
P.O. Box 55
FIN-00301 Helsinki
Tel: +358 9 473 341
Fax: +358 9 714 469

Fees payable to:
National Agency for Medicines
Marketing Authorisations

Method of payment:
Account no. 800014 - 21 979 of Sampo Bank plc, preferably wire transfer (swift-code PSPBFIHH, IBAN number: FI1480001400021979). The proof of payment of the fee should be included to the application. The proof should contain the information on the date of payment, the (proposed) name for the product with the strength and pharmaceutical form, the name of the applicant/marketing authorisation holder, method of procedure (national procedure/mutual recognition/decentralised procedure) and the type of application (new application / type II variation / renewal).

France

Published national rules:
Décret n° 2005-141 du 17 février 2005 pris pour l'application de l'article L.5141-8 du code de la santé publique

Available from address for advice on fees:
AFSSA - ANMV
Agence Nationale du Médicament Vétérinaire
La Haute Marche
Javené B.P. 90203
F-35302 Fougères
Tel: +33 2 99 94 78 82
Fax: +33 2 99 94 78 64
E-mail: enreg@anmv.afssa.fr

Method of payment:
Cheques should be made payable to Agent comptable de l'AFSSA

Germany *For non immunological veterinary products*

Published national rules:
Kostenverordnung für die Zulassung von Arzneimitteln durch das Bundesinstitut für Arzneimittel und Medizinprodukte und das Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)

Available from:
Bundesanzeiger Verlagsgesellschaft m.b.H.
P.O. Box 100534
D-50445 Köln

Address for advice on fees:
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Abteilung 3
Mauerstraße 39-42
D-10117 Berlin
Tel: +49 30 18444-30141
Fax: +49 30 18444-89999

Fees payable to:
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Abteilung 3
Mauerstraße 39-42
D-10117 Berlin

Method of payment:
Payment on request according to calculation of cost (Kostenbescheid).
The Kostenbescheidnummer must always be indicated

For immunological veterinary products

Published national rules:
Tierimpfstoff-Kosten-Verordnung

Available from:
Bundesanzeiger Verlagsgesellschaft m.b.H.
P.O. Box 100534
D-50445 Köln

Address for advice on fees:
Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe
Paul-Ehrlich-Strasse 51-59
D-63225 Langen
Tel: +49 6103 77 1205
Fax: +49 6103 77 123

Fees payable to:
Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe
Paul-Ehrlich-Strasse 51-59
D-63225 Langen

Method of payment:
Payment on request according to calculation of cost (Kostenbescheid).
The Kostenbescheidnummer must always be indicated.

Greece

Published national rules:
Ministerial Decree N°Y6a/11094/97 published in the Official Gazette 235/B/11-3-98.

Available from address for advice on fees:
National Drug Organization
284 Messogion Avenue
Holargos
GR-15562 Athens

Fees payable to:
Bank of Greece (to the account of the National Drug Organization)
26303/8
Foreign Exchange Department – Section C
21 Panepistimiou Avenue
GR-10250 Athens
Payment to be made on application. Proof of payment is necessary.

Address for advice on fees:
Evaluation Division, Section of Veterinary Products, EOF
Mesogion Avenue 284
Holargos
GR Athens 15562
Tel: +30 210 650 72 77 or 6507278 or 6507387
Fax: +30 210 653 75 91

Hungary

Published national rules:
Decree 46/1999. (V. 19.) MARD as modified by decree 78/2004. (V. 4.) MARD on fees of the administrative services in animal health,

Available from:
Website of the Directorate of Veterinary Medicinal Products s
www.ivmp.gov.hu

Fees payable to:
Hungarian State Treasury
IBAN: HU97 10032000-00289782-00000000
Swift code: MANE HU HB

Method of payment:

The applicant is obliged to pay the fee of the procedure - according to the decree 50/2006.(VI.28.) MARD - preceding the submission of the application and the proof of payment has to be attached to the application.. More information is available on the website of DVMP (www.ivmp.gov.hu)

Ireland

Address for advice on fees:
Veterinary Section
Irish Medicines Board
Kevin O'Malley House
Block A, Earlsfort Centre
Earlsfort Terrace,
Dublin 2
Ireland
Tel: +353 1 676 4971
Fax +353 1 676 7836

Fees payable to:
Irish Medicines Board
Kevin O'Malley House
Block A, Earlsfort Centre
Earlsfort Terrace,
Dublin 2
Ireland
Tel: +353 1 676 4971
Fax: +353 1 676 7836

Method and time of payment:
Payment must be made at time of application, by any of the following methods:

1. Electronic Fund Transfer (EFT) to:
   A/C No 33712185 / Sort code: 93-10-12
   IBAN: IE 54 AIBK 931012 33712185
   A/C Name: Irish Medicines Board
   Bank: Allied Irish Bank
   1-3 Lower Baggot Street
   Dublin 2
   Ireland
   Proof of payment must accompany application
2. Irish cheque in € (Euros) drawn on an Irish Bank
3. Bank draft drawn on an Irish Bank in €

Italy

Published national rules:
Registration Taxes
1) Ministry of Health Decree of 19 July 1993 published in the "Gazzetta Ufficiale" no. 172 of 24 July 1993.
2) DLgs n. 193, 06/04/2006, published in the "Supplemento ordinario alle Gazzetta Ufficiale" n. 121, 26/05/2006.

Available from the address for advice on fees:
Ministero della Salute – Direzione Generale della Sanità Animale e del Farmaco Veterinario – UFF. IV DGSA
Piazzale G. Marconi 25
I-00144 Roma
Tel: +39 06 59 94 65 84
Fax: +39 06 59 94 69 49, 59 94 62 17 or 59 94 66 76

Method and time of payment:
Payment must be made at time of application, by any of the following methods:
1) Postal Giro No 12453015 registered to TESORERIA PROVINCIALE DI VITERBO.
2)International fund transfer to:
Tesoreria dello stato di Viterbo – Italia, Poste Italiane di Viterbo – conto corrente postale n. 12453015 ABI code 7601, CAB code 14500 CIN 8
Beneficiary: Ministero della Salute – Dipartimento per la Sanità Pubblica Veterinaria, la Nutrizione e la Sicurezza degli Alimenti – Ufficio IV (DGSA)
3) Bank transfer to:
bank name: Banca d'Italia - Tesoreria Centrale dello Stato
IBAN-code: IT87 N010 0003 2040 0000 0000 350
BIC-code: BITA IT RR XXX
object: Ministero della Salute – Dipartimento per la Sanità Pubblica Veterinaria, la Nutrizione e la Sicurezza degli Alimenti – Ufficio IV(DGSA) - capo XX -capitolo 2230 - art. 14 -_indicate the name of the VMP and the type of application (new marketing authorisation, variation, renewal, etc)

Proof of payment must accompany the dossier. Cheques are not accepted. Payments must be nett of all bank charges.

Latvia

Published national rules:
Order No. 228 of Ministry of Agriculture of 18. June, 2004
and
Price Current for fee of Food and Veterinary Service

Assessment fee payable to:
EUR account:
The Treasury Republic of Latvia, identification number: 90000050138
Beneficiary: Food and Veterinary Service the Republic of Latvia, identification number – 90000064301
Beneficiary's bank: Parekss banka
Branch "Citadele" Kr. Valdemāra iela 1b, Riga, LV-1805
Bank code: 310101708
SWIFT code: PARXLV22
Accont number: LV 54TREL 049102000000B

Method of payment:
An invoice will be sent upon receipt of the application. No payment should be made in advance.
Please make sure that the whole amount of the will be credited to our account net of any charges from the issuing or receiving bank.

Lithuania

Published national rules:
Approved by the decision No. 1253 (05 October, 2004) of the Government of the Republic of Lithuania

Assessment fee payable to:
The payments will have to be transferred in a currency of LTL to:
Beneficiary: **Kauno apskrities valstybine mokesciu inspekcija**
IBAN LT907300010002231764
SWIFT: HABALT22
Legal entity's code 188729019
Beneficiary's credit institution AB bankas "Hansabankas".
AB "Hansabankas"
Address: Savanoriu 19, LT-03502 Vilnius, Lithuania

Method of payment:

Please indicate reference number 5742 and details of payment: registration/renewal/variation/etc. fee.
Please provide the proof of payment together with the application form and the dossier.

Note: If it is not possible to transfer the payment in LTL, please pay in EURO and add 3 Euros to the converted amount.

Luxemburg

Published national rules:
Règlement grand-ducal du 24.12.93 fixant les droits dus pour la mise sur le marché des médicaments

How available:
Sent on request

Address for Advice on Fees:
Villa Louvigny
Division de la Pharmacie et des Médicaments
Allee Marconi
L-2120 Luxembourg
Tel: +352 478 55 94
fax: +352 26 20 01 40 or 26 20 01 47

Fees payable to:
Administration de l'Enregistrement et des Domaines
Plateau du St. Esprit
L-2010 Luxembourg

Method and time of payment:
Proof of payment must accompany the dossier.
Payment must be made through Postal Account No 77 33 70. Cheques are not accepted. Contact person: Mr. Carlo Scholl, Inspector. Tel. : +352 4785594

Malta

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Netherlands

Published national rules (brochure) on request from address for advice on fees:

College ter Beoordeling van Geneesmiddelen
Medicines Evaluation Board
Postbus 16229
2500 BE Den Haag
Tel: +31 70 356 74 00
Fax: +31 70 356 75 15

Information on fees:
Website: www.cbg-meb.nl

Fees payable to:
College ter beoordeling van Geneesmiddelen
Den Haag

Method of payment:
Payment must be made through Account no. 3000.04.710
IBAN: NL62RABO0300004710
Cheques are not accepted. Remittances should quote the product name and the Dutch case number.
No payment in advance, a bill is sent after receipt of the dossier.

Poland

Published national rules:
Rozporządzenie Ministra Zdrowia z dnia 20 lipca 2006 w sprawie sposobu ustalania i uiszczania opłat związanych z dopuszczeniem do obrotu produktu leczniczego weterynaryjnego (Dziennik Ustaw Nr 142 poz 1024)

Assessment fee payable to:
Narodowy Bank Polski Warszawa
Bank account no.: 30 1010 1010 0094 1022 3100 0000
Code BIC NBP- NBPLPLPW

Method of payment:
Proof of payment must accompany the dossier.
Cheques are not accepted. Payments must be net of all bank charges.

Each fee has to be paid on individual form. In the title the procedure name/number should be indicated with the pharmaceutical form of the product, if possible, as well as the company's name.

Portugal

Published national rules:
Decreto-Lei N° 148/2008, de29 de Julho
Diario da República – 1ª série – Nº 145-, 29 de Julho de 2008

Portaria n.º 1444/2008, de 12 de Dezembro

Available from the address for advice on fees:

DGV - Direcção-Geral de Veterinária
Lg. Academia Nacional de Belas Artes 2
1249-105 Lisboa
Tel: +351 21 3239533/9717
Fax: +351 21 3239565

Method and time of payment:
Payment must be made at the time of the application submission, by any of the following methods:

- Cash – treasurer's office of DGV
- Portuguese cheques in € (Euros) made payable to "Instituto de Gestão da Tesouraria e do Crédito Publico" and sent to Direcção Geral de Veterinária,

or by

- Bank deposit/transfer to : Instituto de Gestão da Tesouraria e do Crédito Público
NIB – 0781 0112 000 0000 7784 96
IBAN – PT50 0781 0112 00000007784 96
SWIFT BIC CODE – IGCPPTPL

Bank Name and Address:
Instituto de Gestão da Tesouraria e do Crédito Publico IP
Av. da República, nº 57, 6º Piso
1050-189 Lisboa
Portugal

The amount must be the exact one (net of all bank charges).
It is advisable to initiate the bank transfer approximately 1 week in advance of the submission of the application.
Proof of payment (a copy of the deposit/transfer slip)* must accompany the application and shall **also** be sent to:
Tesouraria da DGV
Lg. Academia Nacional de Belas Artes 2
1249-105 Lisboa
Tel: +351 21 3239500
Fax: +351 21 3239

*Proof of payment must quote the Decreto-Lei N° 148/2008, de29 de Julho, the name of the product, the type of application (MA, Type I variation…etc) and, in case of MRP/DCP the MRP/DCP application number.

Romania

Published national rules
"Order of president of ANSVSA no. 174/2007" published in Official Gazette no. 690/ 11/10/2007
Institute for Control of Biological Products and Veterinary Medicines
39 Dudului Street, sector 6, postal code 060603
Bucharest, Romania

Method and time of payment:

The receipt of fees must be supplied at the same time as the submission of the dossier. Cheques are not acceptable

Please indicate reference number and details of payment: registration/renewal/variation/etc. fee.

For payments in **LEI**:
Trezoreria sector 6, Bucuresti ROMANIA
IBAN : RO 23TREZ7065009XXX000148
COD FISCAL -4267214

For payment in **EURO**:
BANCA COMERCIALA ROMANA
SUCURSALA PLEVNEI
Calea Plevnei nr. 90-92, sector 1, Bucharest ROMANIA
IBAN:RO25RNCB0071011443970002
Cod SWIFT: RNCB ROBU B80-

Spain

Published national rules:
"Ley 66/1997 de 30 de Diciembre 1997 de Medidas Fiscales, Administrativas y del Orden Social".

Available from the address for advice on fees:
Ministerio de Sanidad y Consumo

Agencia Española de Medicamentos y Productos Sanitarios
Parque Empresarial Las Mercedes
C/ Campezo, 1- Edificio 8
28022 Madrid
Fax: +34 91 8225443

Fees payable to:
TESORO PUBLICO. Agencia Española de Medicamentos y Productos Sanitarios

Method and time of payment:
By bank transfer trough bank account n° 0182 9071 03 0203977511
BANCO BILBAO VIZCAYA (BBVA)
Paseo del Prado 18-20
E-28014 MADRID

Each application should be accompaigned by a payment voucher.

Sweden

Published national rules:
State Control of Medicinal Products (Fees) Ordinance (1993:595)
Ordinance on change in the ordinance (1993:595) on fees for the governmental control of medicinal products (SFS 1997:961 and 1998:1813
Medical Products Agency's provision and guidelines (LVFS 1995:12)

Available from:
Fritzes
SE-106 47 Stockholm
Tel: +46 8 690 90 90

Method of payment:
An invoice will be sent upon receipt of the application. No payment should be made in advance.

See also the MPA website: www.mpa.se

Slovakia

Published national rules:
Zákon č.140/98 Z.z. o lieku a zdravotníckych pomôckach a Zákon č. 145/95 Z.z. o správnych poplatkoch, v znení neskorších predpisov.

Available from:
Ústav štátnej kontroly veterinárnych biopreparátov a liečiv (Institute for State Control of Veterinary Biologicals and Medicaments)
Biovetská 34
949 01 Nitra
Tel.: + 421 37 6933511 – 513
Fax: +421 37 6517 915
E-mail: uskvbl@uskvbl.sk
Website: www.uskvbl.sk

Fees payable to:
BANK NAME: Všeobecná úverová banka a.s.
SWIFT: SUBASKBX
Beneficiary´s account No: IBAN: SK 6081800000007000078109
Receiver address: Ústav štátnej kontroly veterinárnych biopreparátov a liečiv
Biovetská 34, P.O.BOX 52/C
949 01 Nitra, Slovakia

Remittance Information: pmt title: 347
invoice No. :……
attn.: MVDr.Hederová Judita

Metod of payment:
The receipt of fees must be supplied at the same time as the submission of the dossier. Cheques are not accepted.

Slovenia

Published national rules:

- Rules on fees (Official Gazette of the Republic of Slovenia, no. 3/2007, available on website: http://www.jazmp.si)
- Act on Administrative fees (Official Gazette of the Republic of Slovenia, no. 138/2006)

Available from:
arszmp@gov.si

Fees payable to:
Bank name: Banka Slovenije
Branch address: Slovenska 35
Town/City: Ljubljana
Post code: 1505
Account number: 01100-6000020296
Ref. No.: 00 760102-401 (Application fees for medicinal use for veterinary use)
Ref.No: 00 760002-403 Annual fees for medicinal products for veterinary use)
IBAN: SI56011006000020296
SWIFT code (BIC): BSLJSI2X
Fees have to be paid prior to submission of the application.
Administrative fees should be paid by means of revenue stamps (fee stamps) attached to the cover letter
Administrative fees can also be paid to:
Bank name: Banka Slovenije
Branch address: Slovenska 35
Town/City: Ljubljana
Post code: 1505
Account number: 01100-1000315637
Ref. No.: 11 27650-7111002
IBAN: SI56011001000315637
SWIFT code: BSLJSI2X
The purpose should be also stated (application for MRP/DCP xxx) and the claimant (Agency for Medicinal Products and Medical Devices of the Republic of Slovenia = JAZMP).

United Kingdom

Published national rules:
The Veterinary Medicines Regulations.
Available to view on our website: www.vmd.gov.uk

Address for information on fees:
Veterinary Medicines Directorate
Finance Revenue Section
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS
United Kingdom
Tel: +44 1932 33 83 78
Fax: +44 1932 33 66 18

Fees payable to:
Veterinary Medicines Directorate
Cashier
Room 231
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS
United Kingdom
Tel: +44 1932 33 83 85
fax: +44 1932 33 66 18

Methods of payment:
Cheques should be made payable to "Defra – Veterinary Medicines Directorate"
Payment by automated credit transfer should quote
a/c no. 65639138 – sort code 60 23 40
International Payments should quote
IBAN GB68 NWBK 6023 4065 6391 38
BIC NWBK GB 2L
All remittances must be made in pounds sterling.
Payments must be nett of all bank charges.

EMEA

European Medicines Agency
7 Westferry Circus
Canary Wharf
GB – LONDON E14 4HB
tel: (44) (0207) 418 8400
fax: (44) (0207) 418 8416

Method of payment:

The EMEA will issue an invoice on the date of the notification of the administrative validation to the Applicant and fees will be payable within 45 days of the date of the said notification. The invoice will be sent to the billing address indicated by the Applicant and will contain clear details of the product and procedures involved, the type of fee, the amount of the fee, the bank account to where the fee should be paid and the due date for payment. Where more than one procedure is processed in a given month a summary invoice or statement will be issued at the end of each month for payment within 30 days of the end of the month.

To facilitate this operation Applicants/Marketing authorisation Holders who are demanding a Purchase Order Number on the EMEA invoice are requested to indicate this Number clearly on the cover letter of a given application. The EMEA will no longer accept separate notifications of Purchase Order numbers, not associated with the dossier. Applicants/Marketing authorisation Holders must state the following sentence on the Cover letter of each application:

Please quote Purchase Order Number …….. on the invoice.

If the Applicants/Marketing authorisation Holders do not require a Purchase Order Number on the EMEA invoice, this should also be clearly stated in the cover letter.

More information on the Application fees in the Centralised Procedure is available on the EMEA Website
http://www.emea.europa.eu/htms/general/admin/fees/feesfaq.htm

EFTA

Iceland

Published national rules:
TARIFF No. 509/2007 for marketing authorisations, annual fees and other licence fees for medicinal products and other related products, collected by Icelandic Medicines Control Agency. Website:
http://www.imca.is/Icelandic_Medicines_Control_Agency/Legislation/Fees/

Available from:
Heilbrigðisráðuneytið
Vegmúla 3
IS-150 Reykjavík
Iceland.

Address for advice on fees:
Lyfjastofnun
The Icelandic Medicine Control Agency (IMCA)
Eiðistorgi 13-15
IS-170 Seltjarnarnes Iceland
Tel. +354 5202100
Fax number: +354 5612170
email: lyfjastofnun@lyfjastofnun.is or imca@imca.is

Fees payable to:
The Central Bank of Iceland, Kalkofnsvegur 1, IS-101 Reykjavík. Bank account no: 0001-26-025017, Iban no: IS480001 2602 5017 5402 696459 Ríkisféhirðir, kt. 540269-6459
Swift address is *sislisre*
In receipt of an application an invoice is sent to the applicant Deposit into bankaccount. Cheques not accepted. All remittances should quote invoice number, the name and address of the applicant and the name of the product. Proof of payment is required before applications can be processed

Norway

Published national rules:
Forskrifter om legemidler

Available from:
Statens legemiddelverk
Sven Oftedals vei 8
NO-0950 OSLO

Fees payable to:
Statens legemiddelverk
Sven Oftedals vei 8
NO-0950 OSLO
Tel: +47 22 89 77 00
Den Norske Bank
P.O. Box 1171, Sentrum
NO-0107 Oslo
Bank account no.: 7694 05 00903
SWIFT: DNBANOKK
IBAN nr NO71 7694 05 00903

10. 'BLUE-BOX' REQUIREMENTS

Additional information on labelling/package leaflet that may be required nationally in accordance with Directive 2001/82/EC is outlined below.

AUSTRIA

Legal status: "Rezept und apothekenpflichtig" (Prescription only, available in pharmacies)

BELGIUM

Legal status

For medicinal products restricted to special prescription (narcotics), a number code assigned by the Minister of Health and a double red line are mandatory. This double red line must be as large as the largest character on the label. The red lines should be parallel, 1 – 3 cm apart and in an angle of 45° starting from the left lower corner to the right upper corner.

Identification

Both a barcode and a national code are accepted on the label, but not required.

BULGARIA

The primary and outer packaging of the VMP containing narcotic substances shall be identified (marked) diagonally by two red lines (strips), while the psychotropic ones shall be marked by two blue strips.

In the cases where the marketing autorisation of VMP has been issued in accordance with the centralized procedure, each authorized or required by the National Veterinary Service (NVS) additional information shall be placed (written) within an area bordered by a frame that shall clearly outline it from all the other data.

The data placed on the primary and on the outer packaging and also in the instruction for use shall be written in Bulgarian language. The labels of the homeopathic VMPs shall involve the note **'Хомеопатичен ветеринарномедицински продукт'**.

The note **'Само за ветеринарномедицинска употреба'** shall be placed on each primary and outer packaging of any VMP.

The data in the instruction for use may be written in several languages, one of which must be Bulgaria, but if only the data written in all these languages are identical.

Where the VMP must be sold and used under veterinarian' s prescription, the note **'По лекарско предписание'** shall be placed on each primary and outer packaging of the VMP concerned, excluding the homeopathic ones. In the other cases the note **'Без лекарско предписание'** shall be placed on each primary and outer packaging of the VMP. All VMPs intended for food production animals and the VMPs, which are subject to special measures to be taken by the veterinarian in order to avoid any risk related to the animals treated or the persons applying the VMP or the environment, shall also be subject to the same requirements, i.e. mandatory identification by the note **'По лекарско предписание'.**

CZECH REPUBLIC

Legal Status

The words "**Indikační omezení**" (prudent use) are required for certain veterinary medicinal products containing antimicrobial substances, in accordance with national law. .

Identification

There is no requirement for the EAN[2] bar codes to appear on the label.
The EAN bar codes are accepted when they are put on the label.

Additional information

Recycling symbols are accepted.

DENMARK

Labelling

Legal status

There is no specific requirement in respect of the legal status.

Identification

The Nordic item number is required on the outer label of all medicinal products, except radiopharmaceuticals, certain vitamins and mineral products, homeopathic, herbal and traditional herbal medicinal products. It is written as "Vnr XX XX XX". A barcode is accepted but not required.

Additional information

Other warnings to be included in the labelling are listed in "Bekendtgørelse nr. 1210 af 7. december 2005 om mærkning m.m. af lægemidler", section 29(2-4) and section 31(4-5).

[2] European Article Number

Package Leaflet

Dosage for each species, route(s) and method of administration	Please notice that your veterinarian may have prescribed the medicinal product for a different therapeutic indication and/or at a different dosage than stated in the package leaflet. Always follow the veterinarian's prescription and the instructions on the dosage label.	Vær opmærksom på, at dyrlægen kan have foreskrevet anden anvendelse eller dosering end angivet i denne information. Følg altid dyrlægens anvisning og oplysningerne på doseringsetiketten.
Adverse reactions: *After the sentence "If you notice any serious effects….."*	Side effects can thereby be reported to the Danish Medicines Agency and the knowledge about side effects can be improved. The owner of the animal can also report side effects directly to the Danish Medicines Agency. You can find guidance on The Danish Medicines Agency's website (see Pharmacovigilance) http://www.laegemiddelstyrelsen.dk/	Bivirkningerne kan dermed blive indberettet til Lægemiddelstyrelsen, og viden om bivirkninger kan blive bedre. Dyrets ejer kan også indberette bivirkninger direkte til Lægemiddelstyrelsen. De/du finder skema og vejledning under Bivirkninger på Lægemiddelstyrelsens netsted http://www.laegemiddelstyrelsen.dk/

FINLAND

Legal status:
There is no requirement for the legal status to appear on the label.

Identification and authenticity:

The Nordic number is required on the label of all medicinal products, except radiopharmaceuticals and herbal remedies. It is written as "Vnr XX XX XX".

A bar code is accepted on the label but not required.

Symbols or pictograms

• Products containing inflammable material must bear the international warning symbol:- 

Advice regarding disposal of unused veterinary medicinal product should be in the package leaflet in both Finnish and Swedish versions.
(The unused product should be taken to a pharmacy or toxic waste disposal plant)
Finnish:
"Käyttämättä jäänyt valmiste toimitetaan hävitettäväksi apteekkiin tai ongelmajätelaitokselle"

In case of common pack for Finland/Sweden the words "För Finland:" should be added before the sentence in Swedish
"Oanvänt läkemedel levereras till apotek eller problemavfallsanstalt för oskadliggörande."

FRANCE

Legal status

The information that the product is a prescription only medicine has to appear in dark ink on a red background rectangle as:

"A NE DELIVRER QUE SUR ORDONNANCE DEVANT ETRE CONSERVEE PENDANT AU MOINS 5 ANS".

The information that the product is a veterinary medicine has to be mentioned as "USAGE VETERINAIRE" written in dark ink in the same red background rectangle.

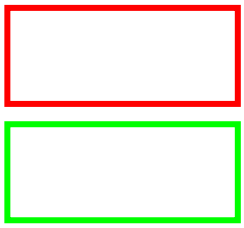
For medicinal products containing an active substance subject to a special regulation in France (narcotic, psychotropic or so called "substances vénéneuses"), it must be added:

- In the red background rectangle " RESPECTER LES DOSES PRESCRITES" and, if the medicinal products is to be administered by a route different than nasal, oral, perlingual, sublingual, rectal, vaginal, urethral or by injection, "NE PAS FAIRE AVALER".
- Above the red background rectangle

  - an empty (white) rectangle with a red border for List I substances

  or

  - an empty (white) rectangle with a green border for List II substances



Identification

If available, the marketing code ("CIP code") and/or the barcode have to appear on the label.

GERMANY

Additional label requirements

Minimum particulars to appear on small immediate packaging units
Small immediate packaging units are defined as containers sized up to and including 10 ml; for greater containers full information is required.

Legal status

The legal status is required on the label:

"apothekenpflichtig" = to appear in the case of medicinal products that are not subject to medical prescription but are only available in pharmacies or from veterinarians

"verschreibungspflichtig" = in case of veterinary medicinal products that are subject to medical prescription only

No separate statement is necessary in the case of products, which are neither prescription only nor pharmacy only.

Identification

The declaration of the constituents has to be stated in accordance with the German Declaration Regulation (Bezeichnungsverordnung).

In case of active substances manufactured by genetechnological means, the active substance and the designation of the genetechnologically modified microorganism or cell line.

In respect of sera, the animal species from which they were obtained, in respect of vaccines, particulars of the host system serving the multiplication process of the virus shall be given.

A barcode is accepted on the label. A distribution number (PZN, i.e. Pharmazentralnummer) is accepted on the label.

Additional information:

In the case of non-prescription medicinal products, instructions for use are required.

In case of samples the indication "unverkäufliches Muster" (sample – not for sale) is required.

A special symbol concerning the recycling of the packaging material is accepted such as the "Grüne Punkt".

National waste disposal instructions, as appropriate, have to be stated.

Package leaflet

The heading "Gebrauchsinformation" (instructions for use) is required.

The declaration of the constituents has to be stated in accordance with the German Declaration Regulation (Bezeichnungsverordnung).

National waste disposal instructions, as appropriate, have to be stated.

In case of medicated premixes the types of feeding stuffs suitable for the manufacture of medicated feeding stuffs should be indicated (according to the German Feed Regulation; Futtermittelverordnung – Anlage 2)

GREECE

Legal status

Veterinary medicinal products subject to a special prescription (narcotics) must have a letter/code

assigned by the Ministry of Health and Welfare with a special colour (read/green) according to the

classification and the following text must appear on the label:

1. Products belonging to list B must mention in red letters:

«Β, χορηγείται με ειδική συνταγή Ναρκωτικών».

2. Products belonging to the exceptions of list B must mention in green letters:

«ΒΣ, χορηγείται με απλή συνταγή Ναρκωτικών».

3. Products belonging to list Γ must mention in red letters:

«Γ, χορηγείται με ειδική συνταγή Ναρκωτικών».

4. Products belonging to the exceptions of list Γ must mention in green letters:

«ΓΣ, χορηγείται με απλή συνταγή Ναρκωτικών».

5. Products belonging to list Δ must mention in green letters:

«Δ, χορηγείται με συνταγή του Ν. 1729/98».

Price: On the outer package of the veterinary medicinal products the price should be written in Greek language <<ΣΥΝΙΣΤΩΜΕΝΗ ΛΙΑΝΙΚΗ ΤΙΜΗ ΠΩΛΗΣΗΣ….ΕΥΡΩ>> and in English language << SUGGESTED PRICE….EURO>>.

HUNGARY

No special requirements beyond the agreed label and package leaflet.

IRELAND

The following requirements are in addition to those of Directive 2001/82/EC as amended and the QRD templates.

Immediate packaging	**Outer packaging**	**Leaflet**
Legal status		
Abbreviation for route of sale and supply, as appropriate: VPO VPO-1 POM POM(E) PS LM CAM	Abbreviation for route of sale and supply, as appropriate: VPO VPO-1 POM POM(E) PS LM CAM	Abbreviation for route of sale and supply and explanatory phrase, as appropriate: VPO Veterinary Practitioner Only VPO-1 Veterinary Practitioner Only POM Prescription Only Medicine POM(E) Prescription Only Medicine (Exempt) PS Pharmacy Sale LM Licensed Merchant CAM Companion Animal Medicine
Identification - nationally authorised products		
*Veterinary Product Authorisation (VPA) number	*Veterinary Product Authorisation (VPA) number	*Veterinary Product Authorisation (VPA) number
Identification – centrally authorised products		
No additional requirements		
Other requirements		
		<u>For nationally authorised immunological products only:</u> If a product is classified as LM the following warning is required 'Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary practitioner is sought'.
Specific National requirements relating to product disposal, if appropriate and as advised by the Competent Authority	Specific National requirements relating to product disposal, if appropriate and as advised by the Competent Authority	Specific National requirements relating to product disposal, if appropriate and as advised by the Competent Authority

*Note: Whilst VPA number is included on this list, exceptionally, in justified cases, it may be omitted.

QRD templates are available at http://www.emea.eu.int/htms/vet/qrd/qrdplt/26556805en.pdf. Annotated versions specifically for MRP and DCP are available on the HEVRA website.

ITALY:

Legal status

For products "subject to prescription":
• when the veterinary medicinal product is intended for food producing animals with a withdrawal period of more than 0 days:
"Da vendersi dietro presentazione di ricetta medico-veterinaria in triplice copia non ripetibile"
(to be sold only with three copies of a non-renewable vet. med. prescription)
• when the veterinary medicinal product is intended for food-producing animals with no withdrawal period or companion animals:
"Da vendersi dietro presentazione di ricetta medico-veterinaria non ripetibile in copia unica" (to be sold only with a non-renewable vet. med. prescription)
or
"Da vendersi dietro presentazione di ricetta medico-veterinaria ripetibile" (to be sold with a renewable vet. med. prescription)
For veterinary medicinal product containing psychotropic substances, the following sentence has to be specified:
"Prodotto soggetto alla disciplina del D.P.R. 309/90 e successive modifiche, tabella n...." (with the correct number specified by the Italian authority on a case by case basis according to "Decreto Presidente della Repubblica 9 ottobre 1990, n. 309" as amended).

Identification

The national identification number and barcodes are required in the label. Any other information about risk hazards, is accepted but not required.

Any other information according to D Lgs n. 193, 06/04/2006, art. 58, section 5, published in the "Supplemento ordinario alla Gazzetta Ufficiale" n. 121, 26/05/2006.

LITHUANIA:

All former national requirements are already included into QRD template and we do not ask for any additional information.

POLAND

Legal status

The following are the specific requirements for the expression of the legal status in the boxed area:

Do stosowania wyłącznie przez lekarza weterynarii = to be used by veterinary surgeon only
Wydawany na podstawie recepty (Rp.). = available on prescription only
Wydawany bez wystawiania recepty = available without prescription

The description of the legal status must be exactly the same as in the Marketing License
(= Pozwolenie na dopuszczenie do obrotu)

Identification

The EAN code is not required on the label.

PORTUGAL

Immediate Label of small containers - Small immediate packaging units are defined as containers sized up to and including 50 ml, for greater containers full information is required.

Withdrawal period

AIM nº

Immediate label (≥ 50 ml) and outer packaging

Items mandatory for both pharmacologicals and immunologicals

1. The legal status is required in the blue box, if not mentioned elsewhere on the label
2. If considered necessary, specific statements, symbols or safety warnings concerning the handling/administration/storage/disposal of the veterinary medicinal product may be required on the label as, for example:

A INJECÇÃO ACIDENTAL É PERIGOSA - ANTES DE UTILIZAR LEIA O FOLHETO INFORMATIVO. (accidental injection is dangerous – Read the package leaflet before use)

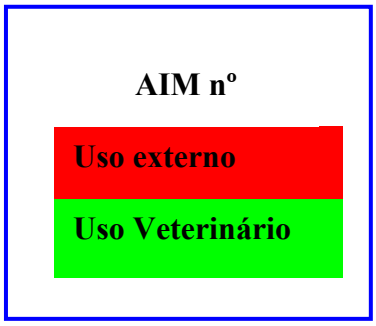
3. AIM nº (Portuguese MA number)
4. "Manter fora do alcance e da vista das crianças"

(Keep out of reach and sight of children) if not mentioned

elsewhere on the label

5. The expression "Uso Veterinário" must be stated in an entirely

green boxed area.



Specific items for Pharmacologicals

1. If applicable, specific statements concerning the administration and/or availability of the veterinary medicinal product may be required on the label as one of the following:

- *"Só pode ser administrado pelo médico-veterinário"* (administered by a veterinarian only)
- "Só pode ser administrado sob controlo do médico veterinário" (to be administered under the responsability of a veterinarian)

2. Veterinary Medicinal Products for external use should state "Uso externo" in a entirely red boxed area on the label.
3. Medicated premixes: "*Só pode ser vendido a unidades de fabrico de alimentos medicamentosos para animais"*

Specific items for IVMP – Immunological Veterinary Medicinal Products

1. The following sentences are mandatory unless authorised otherwise:

"Só pode ser administrado pelo médico veterinário" (to be administered by the veterinarian only)
or
"Só pode ser administrado sob controlo do médico veterinário" (to be administered under the responsability of a veterinarian)

2. Name/address of the local representative/distributor

ROMANIA

Price

There is no requirements for the price to appear on the label and package leaflet

Reimbursement

There is no requirement for the reimbursement conditions to appear on the label.

Legal Status

The legal statutus is required to be expressed on the the label for prescription-only products.

The following mentions must appear in the boxed area :

For medicinal products supplied in pharmacy based on veterinray prescriptions:

-Se elibereaza pe baza – **P-RF**

For medicinal products supplied in pharmacy based on special veterinry prescriptions (narcotics):

-Se elibereaza pe baza de prescriptie medicala speciala – **P-TS**

Symbols or pictograms

Medicinal products containing inflammable material must bear the international warning symbol:- 

SLOVAKIA

Additional Label requirements

Price

There is no requirements for the price to appear on the label and package leaflet

Reimbursement

There is no requirement for the reimbursement conditions to appear on the label.

Legal Status

There are following requirements regarding the Classification for supply on the outer labelling.

In the case that the vet. medicinal product is only subject to medical prescription is required:

Len na predpis veterinárneho lekára.

For product not subject to medical prescription is required:

Bez predpisu veterinárneho lekára.

The words **„indikačné obmedzenie“** (prudent use) are required for certain veterinary medicinal products containing antimicrobial substances, in accordance with national law.

Identification and authenticity

The EAN code is required.

Additional Package Leaflet requirements

The words **„indikačné obmedzenie“** (prudent use) are required for certain veterinary medicinal products containing antimicrobial substances, in accordance with national law.

SLOVENIA

No specific requirements.

SPAIN

- Dispensación con receta veterinaria ○
- Dispensación con receta de estupefacientes ●
- Dispensación de psicótropos  anexo I del RD 2829/1977
- Dispensación de psicótropos  anexo II del RD 2829/1977
- Conservación en frigorífico ✱
- Conservación en congelación✱✱

Deberán figurar las siguientes siglas según el caso:

- ***AV**, cuando el medicamento tenga que ser administrado exclusivamente por el veterinario*

En los dos primeros casos además de las siglas deberá figurar la siguiente leyenda: “Administración exclusiva por el veterinario”.

SWEDEN

Additional label requirements

Price
There is no requirement for the price to appear on the label.

Reimbursement
There are no reimbursement conditions to appear on the label.

Legal status
There is no requirement for the legal status to appear on the label.

Identification and authenticity
The Nordic number is required on the label of all medicinal products, except radiopharmaceuticals and herbal remedies. It is written as “Vnr XX XX XX”.
A bar code is accepted on the label but not required.

Symbol and pictogram
Products containing inflammable material must bear the international warning symbol (See guidelines for the centralised procedure)

UNITED KINGDOM:

Legal Status

1. The medicinal product may only be supplied in accordance **with a prescription:**

POM-V

Medicines may only be prescribed by a registered veterinary surgeon for an animal under his care. The prescription may be dispensed by any registered veterinary surgeon or registered pharmacist.

POM-VPS

Medicines which can be prescribed and supplied by a Veterinarian Surgeon, Pharmacist or a registered Suitably Qualified Person (SQP) or it may be supplied separately by one of the above in accordance with a written prescription from that person.

2. The medicinal product may be sold or supplied **without a prescription**:

NFA-VPS

Medicines which can be supplied without a prescription by a Veterinary Surgeon, Pharmacist or a Suitably Qualified Person (SQP).

AVM-GSL

Medicines which may be supplied by any retailer. Products which do not require specific advice concerning their method of use.

3. Controlled Drug (CD):

Medicinal products considered to be dangerous and likely to be subject to abuse. Additional precautions in respect of storage and supply are required. These products are also **POM-V.**

CD , followed by Sch 2 or Sch 3 as appropriate

Identification
Information for the identification and authenticity are not required on the label. Barcodes are accepted on the label, but are not required.

Additional Information

'Keep out of reach of children'

'Keep the container in the outer carton'

EFTA COUNTRIES

ICELAND

Label

Legal status

There is no requirement for the legal status to appear on the label.

Price

There is no requirement for the price to appear on the label.

Local representative

The local representative may be indicated in the "blue box" on the label by name, telephone number and /or e-mail address and logo (optional). Postal address may be included if space permits (should not interfere with the legibility of the EU text on the outer packaging) and if mentioned in the leaflet.

Identification

The Nordic number is required on the outer label of all medicinal products except radiopharmaceuticals, homeopathics and herbal remedies. It is written as "Vnr XX XX XX" A barcode is accepted on the label but not required.

Additional warnings:

Products containing inflammable material must bear the international warning symbol

Eldfimt + tákn 

English translation: Inflammable + symbol

NORWAY

Label:

Legal status

There is no requirement for the legal status to appear on the label.

Price

There is no requirement for the price to appear on the label.

Local representative

The local representative may be indicated in the "blue box" on the label by name, telephone number and /or e-mail address and logo (optional). Postal address may be included if space permits (should not interfere with the legibility of the EU text on the outer packaging) and if mentioned in the leaflet.

Identification

The Nordic number is required on the outer label of all medicinal products except for radiopharmaceuticals, homeopathics and herbal remedies. It is written as "Vnr XX XX XX". A barcode is accepted on the label but not required.

Additional warnings:

Products containing inflammable material must bear the international warning symbol:

- Brannfarlig + symbol 
- English translation: Inflammable + symbol