EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single market, regulatory environment, industries under vertical legislation
Pharmaceuticals

Brussels,
ENTR/F/2/AW D (2003)

Final – Revision 3

NOTICE TO APPLICANTS

VOLUME 6A

CHAPTER 7

GENERAL INFORMATION

OCTOBER 2003

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

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 Agency for the Evaluation of Medicinal Products), 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 V – General conclusions - Immunological veterinary medicinal products

Part I: Summary of the Dossier consists of:

IA Administrative information including Marketing Authorization particulars, proof of payment, documents on manufacturers' authorisations & 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 Expert reports 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 and Mutual Recognition applications (Key: / = or & = and)

Dossier	AT	BE	DK	FI	FR	DE	EL	IR	IT	LU	NL	PT	ES	SE	UK	EMEA	EFTA NO	EFTA IS
Part IA – Format	DE	FR/NL/ EN	DK/ EN	FI/SE/ EN	FR	DE/EN	EL	EN	IT	FR/DE/ EN	NL/EN/ DE	PT& FR/EN	ES& EN[6]	SE/ EN	EN	EN[9]	NO/E N	IS/ EN
Part IB – SPC	DE	FR/NL/[1] EN	DK[2]	FI	FR/EN	DE	EL	EN	IT	FR/DE/ EN	NL	PT	ES& EN[6]	SE	EN	All[9]	NO	IS
Part IB – Package insert & Labels	DE	FR/NL[1]	DK[2]	FI & SE	FR/EN	DE	EL	EN	IT	FR/DE/ LU	NL	PT	ES& EN[6]	SE	EN	All[9]	NO	IS[10]
Part IC	DE/ EN	FR/NL/ EN	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT[3]	FR/DE/ EN	NL/EN/ DE	PT[5]	ES& EN[6]	SE/ EN	EN	EN[9]	NO/E N	EN
Part II	DE/ EN	FR/NL/ EN/DE	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/ EN[4]	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[8]	SE/ EN	EN	EN[9]	NO/E N	EN
Part III	DE/ EN	FR/NL/ EN/DE	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/ EN[4]	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[7]	SE/ EN	EN	EN[9]	NO/E N	EN
Part IV	DE/ EN	FR/NL/ EN/DE	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/ EN[4]	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[7]	SE/ EN	EN	EN[9]	NO/E N	EN
Written responses	DE/ EN	FR/NL/ EN/DE	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/EN	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[8]	SE/ EN	EN	EN[9]	NO/E N	EN
Variations																		
Application form	DE	FR/NL/ EN	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL	EN	IT	FR/DE/ EN	NL/EN/ DE	PT	ES& EN[6]	SE/ EN	EN	EN[9]	NO/E N	IS /EN
Type I – documentation	DE/ EN	FR/NL/ EN	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/ EN[4]	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[8]	SE/ EN	EN	–	NO/E N	EN
Type II – documentation	DE/ EN	FR/NL/ EN	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/ EN[4]	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[8]	SE/ EN	EN	–	NO/E N	IS/ EN
Written responses	DE/ EN	FR/NL/ EN	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/EN	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[8]	SE/ EN	EN	–	NO/E N	EN
Renewals	DE/ EN	FR/NL/ EN	DK/ EN	FI/SE/ EN	FR/EN	DE/EN	EL/ EN	EN	IT/EN	FR/DE/ EN	NL/EN/ DE	PT/FR/ EN	ES/EN[8]	SE/ EN	EN	EN[9]	NO/E N	IS/ EN

1. The MAH is obliged to choose, at the time of submission, either Dutch or French. After a MA is granted, the MAH must translate SPC, Package Insert and labels into the other national languages (Dutch **or** French **and** German). The responsibility for the correct translation rests with the MAH.
2. EN is accepted for some classes of product.
3. EN/FR plus Italian translation.
4. If the English version is not available, a French version could be accepted.
5. Expert Reports EN/FR plus Portuguese translation (excluding annexes).

6. For national applications, only Spanish version can be accepted. For Mutual Recognition applications, Spanish and English versions are mandatory.
7. For national applications, English is acceptable if a Spanish abstract of all studies and conclusions is included.
8. For national applications, Part II: in Spanish, English is only accepted for Part IIC [(1.1.1, 1.2.1, 1.2.3, 1.2.4, 1.2.5, 1.2.7, 2.1.1) + E(2.2) , tabular formats and graphics]; Part III and Part IV: English is only acceptable if a Spanish abstract of all studies and conclusions is included. For Mutual Recognition applications, the same is applicable to the additional copy of Part II.
9. 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.
10. EN is accepted on labels and package inserts for some products, e.g. some products only administered by veterinarians

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 and Mutual Recognition Procedures

	AT	BE	DK	FI	FR	DE	EL	IR	IT	LU	NL	PT		ES	SE	UK	EMEA	EFTA	
												Pharm	Immun					NO	IS
Full dossier	1[1]	1	1	1	2[3]	3[8]	1	1[9]	2[10]	1[11]	4[21]	1[13]	3	4	1	3	-[23]	1	1[1]
Additional: Part IA	2	4	0[16]	1	24	1	2	1[9]	3	1	1	7	7	7[17]	1[18]	2		1	
Additional: IB SPC, package insert, etc.	2	4	0[16]	1	24		2	1[9]			1	7	7	7[17]	1[18]	2		1	
Additional: IC Expert rep.	2	4	2[16]	1	24		2	1[9]	3		1	3	7	7[17]	1[18]	2		1	
Additional: Part II	2	2		1[19]							1[22]			1					
Biological/Biotech.		2		-		3		1[4]	2[10]			1							
Additional: Part III				0[1]									1		1[18]				
Additional: Part IV				0[1]	1[4]														
Written responses	2[2]	2[2]	2	1[20]	2[5]	4	2	1	2[10]	1[12]	5[21]	3	2	4	1	4		1[2]	1
Variations																			
Application form	3	2	1	2	1[6]	3	2	2[14]	1		5	3[13]	3	3	1	2[15]		1	1
Type I – documentation	2	2	1	1	1	3	1	2[14]	1		5	3[13]	3	3	1	2		1	1
Type II – documentation	2	2	1	1	2[5]	3	1	2[14]	2[10]		5	3[13]	3	3	1	4		1	1
Supplementary info	2	2	1	1		3	1	2[14]	1		5	3[13]	3	3	1				1
Additional SPC/Package insert	8	1		1		3			1			3[13]	3						
Additional Labels	4	1		1		3			1			3[13]	3						
Additional statement on qualitative and quantitative composition	4			-		3			1			3[13]							

1. Part III and Part IV to be held available by the applicant for supply on request
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 per species in multispecies vaccines
4. For non-immunologicals
5. 1 extra copy for non-immunologicals on the response to Part IV. 3 except 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 BFAV Insel Riems, for all other vaccines to Paul-Ehrlich-Institute
9. For immunological products: only one copy of the full dossier is required and must be submitted to the Irish Medicines Board, the additional Part IA, IB and IC must be submitted directly to the Department of Agriculture and Food
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. One extra copy for non-immunologicals should be provided to INFARMED

14. For immunological products: one copy of the required documentation must be submitted to the Irish Medicines Board and one copy to the Department of Agriculture and Food
15. 2 copies for Type I variations and 4 copies for Type II variations
16. Denmark (whenever possible) requires an additional CD-rom version of all section of Part I
17. Only for Mutual Recognition applications copies in Spanish
18. Only for veterinary medicinal products for use in food-producing animal species
19. For immunologicals, 1 extra copy or Part II
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. Less for some applications. For detailed information, consult the Dutch website: www.brd.agro.nl. One full copy of the dossier and the written responses may be submitted on CD-rom instead of on paper.
22. Only for pharmaceuticals
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.

3.2 National and Mutual Recognition Procedures: "additional data" requested

Additional DATA requested	AT	BE	DE	DK	EL	ES	FI	FR	IR	IT	LU	NL	PT	SE	UK	EFTA	
																NO	IS
Statement compliance with GMP [2]		X			X						X		X				
Copy of manufacturer's.authorisation (if manufacturing within EU)		X		X	X						X		X	X		X	
Verification of Approved GMP-inspection by EU-member state (if manufacturing outside EU)				X									X	X		X	
contract between MAH in RMS and applicant					X												
authorisation "declaration of consent"					X						X		X				
certificate for the MA transfer to local subsidiary					X						X		X				
a certified copy of the marketing authorisation granted by the RMS					X						X		X				
Yellow/Pink card for each authorisation number 1		X															
Marketing authorisation forms (2 original standard forms for each authorisation number) 1		X															
Contract between marketing authorisation holder in Belgium and responsible of batch release		X															

1. Standard cards and forms can be obtained from the Secretariat of the Belgian Medicines Commission.
2. For each pharmaceutical form, for manufacturers outside Belgium.

3.3 National and Mutual Recognition 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*'.

Renewal	**AT**	**BE**	**DE**	**DK**	**EL**	**ES**	**FI**	**FR**	**IR**	**IT**	**LU**	**NL**	**PT** Pharm	**PT** Immun	**SE**	**UK**	**E F** ***IS***	**T A** ***NO***
European renewal application form	2	3	3	1	2	3	2	4	2	1	1	5	7[2]	7	4	2	1	1
PSUR, incorporating compiled data on 5 years (4.5 years for the first renewal)	2	1	3	1	1	3	1	4	1	1	1	2	7	7	1	1	1	1
Clinical expert report/statement that addresses the current risk/benefit of the product	2	1	3	1	1	3	1	4	1	1	1	2	7	7	1	2	1	1
Current mutually recognised SPC	2	2	3	1	1	3	2	4	2	1	1	5	7[3]	7	1	2	1	1
Proposed SPC	2	2	3	1	1	3	2	4	2	1	1	5	7[3]	7	1	2	1	2
Commitment to take account of new studies considered necessary by the expert through the variation procedure after the renewal process is complete	2	1	3	1	1	3	2		1	1		5	7	7	1	2	1	1
Copy of an updated statement of compliance with the GMP from the competent authority (not older than 3 years)		1	2 or 3[1]	1		3	2		1	1	1	2		7	1		1	1
PL and label text relevant to each member state, for national approval only	2	2	3	1	1	3	2	4	2	1		5	7[4]	7	1	2	1	2
Payment of the national fee	NO	YES	NO	YES[5]	YES	YES	NO	YES	NO	YES	NO	YES	YES	YES	YES[5]	NO	YES	YES

1. Three copies for applications concerning immunological veterinary medicinal products to the Paul-Ehrlich-Institute
2. Application form should be in Portuguese
3. One copy must be in Portuguese
4. Portuguese only
5. The fee will be invoiced by the Danish Medicines Agency/Swedish Medical Products Agency

3.4 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 (EMEA/CVMP/008/95)
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[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 EMEA will always inform applicants of the exact number of copies required by the CVMP members, after validation of the application and adoption of the timeframe for the evaluation.

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 or type I following a type II procedure.

3.5 Applications in the Centralised procedure (renewal):

Renewal	EMEA	Rapp Co-Rapp	Other CVMP members[1]
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 13 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

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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
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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 .....

Abridged application	Yes	No
Application according to Directive 2001/82/EC Article13 point 1(a)i		
Letter of consent from the holder of the authorisation of the original proprietary medicinal product for reference to		
Part III	O	O
Part IV	O	O
Application according to Directive 2001/82/EC Article 13 point 1(a)iii		
Evidence that an essentially similar product has been authorised within the Community in accordance with Community provision in force for not less than six/ten years	O	O
Evidence that an essentially similar product is marketed in the Member State for which an application is made	O	O
For immunological veterinary medicinal products		
Part V General Conclusions acceptable	O	O
Not acceptable for reasons		

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.

5.1.1 National and Mutual Recognition applications

Specimens or mock-ups of the sales presentation, together with a proposal for the package leaflet, should be translated into the national language(s) of the Member State concerned with the application.

5.1.2 Applications in the Centralised Procedure

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

Further to the implementation of the "New product information linguistic review process" (http://www.emea.eu.int/index/indexv1.htm), applicants should provide the EMEA with mock-ups and/or specimens in accordance with the following procedure[1]:

New marketing authorisation procedures:

At submission (Day 0)
One English mock-up (preferably in colour) and one multi-lingual mock-up ("worst-case") of the outer and inner packaging for each pharmaceutical form in the smallest pack-size must be included in Part I of the application.

After adoption of the CVMP opinion (Day 210)
A reduced mock-up package and package insert will have to be submitted by Day 260 for every country where marketing is proposed. 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. The EMEA will perform the mock-up check in 30 days in parallel to the Standing Committee consultation.

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 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.

Before launch of the marketing of the veterinary medicinal product

[1] Please note that a working group at the EMEA is currently reviewing the overall mock-up & specimen checking process for all types of applications. The requirements mentioned below can therefore only be seen as an 'interim' arrangement, awaiting final proposals from the working group.

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 Belgium, Germany, Italy, Luxembourg, Portugal, 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.

REQUIREMENTS FOR SAMPLES IN THE MEMBER STATES

Number of samples	BE	DE	EL	ES	IT	LU	PT	SE	**EFTA**	
									NO	IS
Finished medicinal product	**H**	**B, F**	**G**	**A**	**A**	**A**	**A, B, C and J**	**A**	**B**	**C**
All active substances	**I**		**G**			**A**	**B, C**	**E**	**B**	
Non-pharmacopoeial active substances	**D**		**G**							
Non-active substances	**D**		**G**							

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) For all medicinal products the Paul-Ehrlich-Institut is competent for (sera, vaccines, allergens and blood products) samples must be supplied at the same time as the submission of the dossier.

G) Samples should be made available on request

H) 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.

I) 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.

J) For immunological veterinary medicinal products, the samples shall be supplied to the Direcção-Geral de Veterinária at the same time as the submission of the dossier.

PROVISION OF SAMPLES OF NON-IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Number of samples	AT	BE	ES	EL	FR	LU	SE
Finished product	x	1*	x	x	x	1*	1
All active substances	x						x
Only active substances for which the applicant has introduced a monograph		2x					
Non-active substances for which the applicant has introduced a monograph		2x					

Notes

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

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, DK, DE, FI, IR, IS, IT, NL, NO, PT and UK, samples should be provided only upon request of the competent authorities.

PROVISION OF SAMPLES OF IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

Number of samples	AT	BE	DE	ES	FR	EL	PT	SE
Finished product	x	1*	x	x	x	x	x	1
All active substances	x							
Only active substances for which the applicant has introduced a monograph		2x						
Non-active substances for which the applicant has introduced a monograph		2x						

Notes

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

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, DK, FI, IR, IS, IT, LU, NL, NO, and UK, samples should be provided only upon request of the competent authorities.

6. LIST OF OFFICIAL JOURNALS

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

AUSTRIA

Sanitätverwaltung
Mitteilungen der Österreichischen
Verlag Walter Hätzenberger Ges.m.b.H.
Hauptstrasse 93
A-2384 Breitenfurt

BELGIUM

Belgisch Staatsblad
Leuvensestraat 40-42
B-1000 Brussel

Moniteur Belge
Rue de Louvain 40-42
B-1000 Bruxelles

DENMARK

Statstidende
Otto Mønsteds Gade 3,
DK-1571 København V

FINLAND

Virallinen Lehti, Officiella tidningen
Oy Edita Ab/Virallinen Lehti
P.O. Box 745
FIN-00043 Edita

FRANCE

Journal Officiel de la République Française
Rue Desaix
F-75727 Paris CEDEX 15

GERMANY

Bundesanzeiger Verlags GmbH
Postfach 10 05 34
D-50445 Köln

GREECE

Ephimeris Kyvernisseos Ellenikis Dimokratias
(Official Journal, Government Publications)
Kapodistriou 34
EL-Athens

IRELAND

Iris Oifigiúil, Government Publications Sale Office
Sun Alliance House
Molesworth Street
IRL-Dublin 2

ITALY

Gazzetta Ufficiale della Repubblica Italiana
Istituto Poligrafico e Zecca dello Stato
Piazza G. Verdi 10
I-00198 Roma

LUXEMBURG

Mémorial
Service Central de Législation

	Boulevard F. D. Roosevelt L-2450 Luxembourg
NETHERLANDS	**Nederlandse Staatscourant** Postbus 20014 NL-2500 EA Den Haag
PORTUGAL	**Diario da Republica** Casa da Moeda EP Rua D. Francisco Manuel de Melo 5 P-1092 Lisboa Codex
SPAIN	**Boletin Oficial de Estado** Trafalgar 27 E-28010 Madrid
SWEDEN	**Post-och Inrikes Tidningar** Barnängsgatan 21 P.O. Box 4731 SE-116 92 Stockholm

UNITED KINGDOM

London Gazette	**Edinburgh Gazette**	**Belfast Gazette**
The Stationery Office Ltd The London Gazette PO Box 7923 London SE1 5ZH	HMSO Office of Edinburgh Gazette 71 Lothian Road Edinburgh EH3 9AZ	The Stationery Office IBD House 64 Chichester Street Belfast BT1 4PS

EUROPEAN UNION	**Official Journal of the European Communities** Office for Official Publications of the European Communities 2, rue Mercier L-2985 Luxemburg
EFTA	
Iceland	**Lögbirtingablaðið** Síðumúli 29 150 Reykjavík
Norway	**Norsk Lysingsblad** Postboks 177 NO-8503 NARVIK

7. ADDRESSES FOR DELIVERY OF THE DOSSIER AND SUBSEQUENT CORRESPONDENCE

Austria

Bundesministerium für Arbeit, Gesundheit und Soziales
Abteilung VIII/C/19
Stubenring 1
A-1010 Wien
Tel: (43) (1) 71172-4655; fax: (43) (1) 714 92 22

Belgium
NL/FR

Federal Public Service Health, Food Chain Safety and Environment
Bischoffsheim 33, 1st floor
B-1000 Brussels
Tel: (32) (2) 227 55 00 (general)/227 55 10; fax: (32) (2) 227 55 31
Telex: 25768 MVGSPF B

Denmark

Lægemiddelstyrelsen
Frederikssundsvej 378
DK-2700 Brønshøj
Tel: (45) 44.88.91.11; fax: (45) 44.94.02.37

Finland

National Agency for Medicines
Marketing Authorisations
Mannerheimintie 166
P.O. Box 55
FIN-00301 Helsinki
Tel: + (358) 9 4733 41; fax: + (358) 4733 4355

France

CNEVA – Agence Nationale du Médicament Vétérinaire
BP 203
F-35302 Fougères
Tel: (33) 2 99 94 78 60; fax: (33) 2 99 94 78 64
E-mail: vafo30@calvacom.fr

Germany

Non immunological veterinary medicinal products
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Abteilung 3
Diedersdorfer Weg 1
D-12277 Berlin
Tel: (49) (1888) 84 12 23 64; fax: (49) (1888) 84 12 29 55

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:
BFAV Insel Riems
Bundesforschungsanstalt für Viruskrankheiten der Tiere

Boddenblick 5a
D-17498 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

Ireland

Non immunological veterinary medicinal products
Irish Medicines Board
Block A, Earlsfort Centre
Earlsfort Terrace,
IRL-Dublin 2
Tel: (353) (1) 676 49 71-7; fax: (353) (1) 676 84 90

Immunological Veterinary medicinal products
Department of Agriculture and Food
Agriculture House
Kildare Street
IRL-Dublin 2
Tel: (353) (1) 607 2000; fax: (353) (1) 661 62 63

Italy

Immunological and non immunological veterinary medicinal products
Ministero della Salute
Direzione Generale della Sanità Pubblica Veterinaria, degli Alimenti e della Nutrizione – UFF. XI
Piazzale Marconi 25
I-00144 Roma EUR
Tel: (39) (06) 59 94 35 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:
Laboratorio di Medicina Veterinaria
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

Luxemburg

Villa Louvigny
Division de la Pharmacie et des Médicaments
Allee Marconi
L – 2120 LUXEMBURG
Tel: (352) 478 55 95; fax: (352) 26 20 01 40 or 26 20 01 47

Netherlands

Bureau Registratie Diergeneesmiddelen
P.O. Box 289
NL-6700 AG Wageningen

Tel: (31) (0)317 46 57 30; fax: (31) (0)317 42 31 93
Visiting address:
Bureau Registratie Diergeneesmiddelen
Haagsteeg 2
NL-6708 PM Wageningen

Portugal

Non immunological veterinary medicinal products
INFARMED – Instituto Nacional da Farmácia e do Medicamento
Parque da Saúde de Lisboa
Avenida do Brasil, 53
1749-004 LISBOA
PORTUGAL
Tel.: (351) (21) 7987100; Fax: (351) (21) 7987316
E-mail : infarmed@infarmed.pt
Website : www.infarmed.pt

and: :
Direcção Geral de Veterinária
Lg da Academia Nacional de Belas Artes 2
1294-105 Lisboa
Tel: (351) (21) 3239533; fax: (351) (21) 3239565

Immunological veterinary medicinal products
Direcção Geral de Veterinária
Lg da Academia Nacional de Belas Artes 2
1294-105 Lisboa
Tel: (351) (21) 3239533; fax: (351) (21) 3239565

Spain

Ministerio de Sanidad y Consumo
Agencia Española del Medicamento
Paseo del Prado 18-20
E-28014 MADRID
Fax: (34) (91) 596 40 74

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

United Kingdom

Veterinary Medicines Directorate
Information Management Section
Woodham Lane
New Haw
NR. Addlestone
Surrey KT15 3LS
United Kingdom
Tel: (44) 19 32 33 84 44; fax: (44) 19 32 33 66 18

EMEA European Agency for the Evaluation of Medicinal Products (EMEA)
7 Westferry Circus
Canary Wharf
UK-London E14 4HB
Tel: (44) (171) 418 84 00; fax: (44) (171) 418 84 16

EFTA

Iceland Lyfjastofnun
P.O. Box 180
Eiðistorg 13 – 15
172 Seltjarnarnes
Iceland
tel : (354) 520 2100
fax : (354) 561 2170
email : lyfjastofnun@lyfjastofnun.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

8. ADDRESSES FOR RECEIPT OF FEES AND TERMS FOR PAYMENT

Austria

Published national rules – Gebührentarif:
Available from:
Bundesministerium für Arbeit, Gesundheit und Soziales
Abteilung VIII/C/19
Stubenring 1
A-1010 Wien
Tel: (43) 1 71172 4655; fax: (43) 1 714 92 22

Address for advice on fees
Bundesministerium für Arbeit, Gesundheit und Soziales
Abteilung VIII/C/19
Stubenring 1
A-1010 Wien
Tel: (43) 1 71172 4655; fax: (43) 1 714 92 22

Fees payable to:
Bundesministerium für Arbeit, Gesundheit und Soziales
P.S.K. Account No 50 70 004 – BLZ. 60000

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

Belgium

Published national rules:
K.B. van 3.7.1969 betreffende de registratie van geneesmiddelen
A.R. du 3.7.1969 relatif à l'enregistrement des médicaments
(text available only in Dutch and French)

Available from address for advice on fees:
Federal Public Service Health, Food Chain Safety and Environment
Directorate-General Public Health Protection: Medicinal Products
Secretary of Medicines Commission
Bischoffsheim 33, 1st floor
B-1000 Brussels
Tel. (32) (2) 227 55 10 ; Fax. (32) (2) 227 55 31

Fees payable to:
De Algemene Farmaceutische Inspectie – Vergoedingen
Inspection générale de la Pharmacie – Redevances
C.A.E./R.A.C.
B-1010 Brussel
Tel. (32) (2) 210 63 85, Fax. (32) (2) 210 49 22
On Postal Account number (PRK – CCP) 679-2005949-86

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

Denmark

Published national rules:
Indenrigs- og Sundhedsministeriets bekendtgørelse nr. 1133 af 13. december 2002 om afgifter for lægemidler og lægemiddelvirksomheder

Available from address for advice on fees:
Lægemiddelstyrelsen
Frederikssundsvej 378
DK-2700 Brønshøj, Danmark
Tel: +45 44 88 91 11

Fees payable to:
Lægemiddelstyrelsen
Frederikssundsvej 378
DK-2700 Brønshøj, Danmark
Tel: +45 44 88 91 11

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

Finland

Published national rules:
Decision of the Ministry of Social Affairs and Health concerning activities of the National Agency for Medicines subject to fees, No 709

Available in internet www.nam.fi **and also from:**
National Agency for Medicines
Department of General Affairs
Mannerheimintie 166
P.O. Box 55
FIN-00301 Helsinki

Tel: (358) 9 473 341; fax: (358) 9 4733 42 67

Fees payable to:
National Agency for Medicines
Marketing Authorisations

Method of payment:
Account no. 800014-21 979 of Leonia Bank plc., preferably with transfer (swift code PSPBFIHH). The date of payment of the fee should be noted on the application and proof of payment, e.g. a copy of the payment slip shall be appended to the application. The post-giro must contain the name proposed for the product, its strength and pharmaceutical form and the name of the applicant and method of processing (national procedure/mutual recognition).

France

Published national rules:
Décret n° 94-601 du 12 juillet 1994 portant application de l'article L-617-5 du Code de la Santé Publique

Available from address for advice on fees:
CNEVA
Agence Nationale du Médicament Vétérinaire
BP 203
F-35302 Fougères CEDEX
Tel: (33) 2 99 94 78 82; fax: (33) 2 99 94 78 88; e-mail: vafo30@calvacom.fr

Method of payment:
Cheques should be made payable to Agent comptable du CNEVA

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
Diedersdorfer Weg 1
D-12277 Berlin
Tel: (49) (1888) 84 12 1210; fax: (49) (1888) 84 12 2956

Fees payable to:
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Abteilung 3
Diedersdorfer Weg 1
D-12277 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

Ireland

Address for advice on fees:
Veterinary Section
Irish Medicines Board
Block A, Earlsfort Centre
Earlsfort Terrace,
IRL-Dublin 2
Tel: (353) (1) 676 4971; fax (353) (1) 676 8490

Fees payable to:
Irish Medicines Board
Block A, Earlsfort Centre
Earlsfort Terrace,
IRL-Dublin 2
Tel: (353) (1) 676 4971; fax: (353) (1) 676 8490

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
   A/C Name: Irish Medicines Board
   Bank: Allied Irish Bank
   1-3 Lower Baggot Street
   IRL-Dublin 2
   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) Decreto legislativo of 24 February 1997 n. 47, published in the "Supplemento ordinario alle Gazzetta Ufficiale" n. 54 of 6 March 1997.

Available from the address for advice on fees:
Ministero della Salute – Direzione Generale della Sanità Pubblica Veterinaria, degli Alimenti e della Nutrizione – UFF. XI
Piazzale G. Marconi 25
I-00144 Roma
Tel: (39) (06) 59 94 35 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 through Postal Giro No 12453015 registered to TESORERIA PROVINCIALE DI VITERBO.
Proof of payment must accompany the dossier. Cheques are not accepted.

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

Netherlands

Published national rules (brochure) on request from address:
Bureau Registratie Diergeneesmiddelen
Postbus 289
NL-6700 AG Wageningen
Tel: (31) (0)317 46 57 30; fax: (31) (0)317 42 31 93

E-mail: BRD@BRD.AGRO.NL

Website: www.BRD.AGRO.NL

Information on fees:

Website: www.BRD.AGRO.NL

Fees payable to:
Bureau Registratie Diergeneesmiddelen
NL-6700 AG Wageningen

Method of payment:
Payment must be made through Postal Cheque Account no. 1041759. Cheques are not accepted. Remittances should quote the product name and the Dutch application number.

Portugal

Non-immunological veterinary medicinal products

Published national rules:

Portaria Nº586/99 de 2 de Agosto
Diario da República – I – Série B, Nº178, 02-08-99,

Available from the address for advice on fees:

Direcção-Geral de Veterinária
Lg. Academia Nacional de Belas Artes 2
1294-105 Lisboa
Tel: (351) (21) 3239533; fax: (351) (21) 3239565; telex: 14818 VETERI-P

Fees payable to:

Money order or bank deposit (cheques are not accepted) on:
(Bank): Caixa Geral de Depósitos
(Account name): Comissão Técnica de Medicamentos Veterinários
(Account number): 0697/801871-026

NIB – 003506970080187102667

Confirmation of deposit should be sent to:
Direcção-Geral de Veterinária
Lg. Academia Nacional de Belas Artes 2
1294-105 Lisboa
Tel: (351) (21) 3239500; fax: (351) (21) 3239565

Method of payment:

Proof of payment must accompany each copy of the dossier deposited in Direcção Geral de Veterinária and INFARMED and must quote the name of the product and, in case of mutual recognition procedure, the MR application number. The amount must be the exact one, i.e. all bank taxes charged by the bank in the country of origin and by the Portuguese bank shall be supported by the applicant.

Immunological veterinary medicinal products

Published national rules:
Decreto-Lei N° 245/2000 de 29 de Setembro
Diario da República – I – Série A, Nº226, 29-09-2000

Available from the address for advice on fees:

Direcção-Geral de Veterinária
Lg. Academia Nacional de Belas Artes 2
1294-105 Lisboa
Tel: (351) (21) 323 95 33; fax: (351) (21) 3239565; telex: 14818 VETERI-P

Fees payable to:
Money order or bank deposit (cheques are not accepted) on:
(Bank): Caixa Geral de Depósitos
(Account name): Comissão Técnica de Medicamentos Veterinários
(Account number): 0697/801871-026

NIB – 003506970080187102667

Method of payment:

Proof of payment must accompany the application and must qoute the name of the product and, in case of mutual recognition procedure, the MR application number. The amount must be the exact one, i.e. all bank taxes charged by the bank in the country of origin and by the Portuguese bank shall be supported by the applicant.

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 del Medicamento
Paseo del Prado 18-20
E-28014 Madrid
Fax: (34) (91) 596 40 74

Fees payable to:
TESORO PUBLICO. Agencia Española del Medicamento

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

Fees payable to:
Postal account
Postgirot Sweden International
SE-105 06 Stockhom
SWIFT: PGSI SESS
Telex: 10185 pgint s
Postal Giro account no. 78 80 56-0
Bank transfer
Skandinaviska Enskilda Banken
SE-106 40 Stockholm
SWIFT: ESSESESS
Bank account no. 5439-1001225

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

United Kingdom

Published national rules:
The Medicines (Products for Animal Use – Fees) Regulation 1998; S.I. 1998/2428

Available from:
Her Majesty's Stationery Office
P.O. Box 276
London
SW8 2DR
United Kingdom
Cost: £ 4.70 + postage

Address for advice on fees:
Veterinary Medicines Directorate
Finance Revenue Section
Woodham Lane
New Haw
NR. Addlestone
Surrey
KT15 3LS
United Kingdom

Tel: (44) 19 32 33 83 72
Fax: (44) 19 32 33 66 18

Fees payable to:
Veterinary Medicines Directorate
Cashier
Room 231
Woodham Lane
New Haw
NR. Addlestone
Surrey
KT15 3LS
United Kingdom

Tel: (44) 19 32 33 83 85
fax: (44) 19 32 33 66 18
Methods of payment:
Cheques should be made payable to "MAFF – Veterinary Medicines Directorate"
Payment by automated credit transfer should quote
a/c no. 65639138 – sort code 60 23 40
All remittances must be made in pounds sterling.

EMEA

European Agency for the Evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
GB – LONDON E14 4HB
tel: (44) (0207) 418 8400
fax: (44) (0207) 418 8416

Method of payment
The EMEA must receive the full application fee in EUROs (net of all bank charges) in order for an application to be validated. Therefore it is advisable to initiate the bank transfer approximately 1 week in advance of the submission of the application.

The EMEA banking reference is as follows:
Lloyds TSB Plc
City International Branch, PO Box 72, Bailey Drive,
Gillingham Business Park,
Kent, ME8 0LS
Sort code: 30-00-02
A/C: 59007357 in the name of EMEA "application fees" account.
Swift code: Loyd GB 2L CTY

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

EFTA

Iceland

Published national rules:
Reglugerð um skráningu-, árgjöld og önnur leyfisgjöld.

Available from:
Heilbrigðis- og tryggingamálaráðuneytið
Laugavegi 116
105 Reykjavík
Iceland.

Address for advice on fees:
Lyfjastofnun
P.O. Box 180
Eiðistorgi 13-15
170 Seltjarnarnes Iceland
tel. (354)- 5202100
fax number: (354)-5612170
email : lyfjastofnun@lyfjastofnun.is
website : www.lyfjastofnun.is

Fees payable to:
The Central Bank of Iceland
Bank account no.: 0001-26-025017,
Ríkisféhirðir, kt. 540269-6459
Swift address is: ***sislisre***
In receipt of an application an ivoice is sent to 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
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