VETERINARY MEDICINAL PRODUCTS (FEES) (AMENDMENT) REGULATIONS OF 2006 AND 2012

ANNEX I

[Regulation 3(1)(α)]

Fees for market authorizations for veterinary medicinal products

NATIONAL MARKETING AUTHORIZATIONS

Type of application	**Type of veterinary medicinal product**	**Fees for submitting the application in Euros (€)**
New marketing authorization	**Full applications**	
	Full application for a marketing authorization, according to Article 10 of the National Legislation or bibliographic application according to Article 13 of the National Legislation	500
	Extension of the marketing authorization of the above products (line extension or not)	300
	Simplified applications	
	Application for a marketing authorization according to Article 12 of the National Legislation. (essentially similar veterinary medicinal products – assent or expiration of the period of exclusiveness of the data)	400
	Extension of the marketing authorization of the above products (line extension or not)	350
Renewal of the marketing authorization	**For all the veterinary medicinal products**	350
Variation of the marketing authorization	**For all the veterinary medicinal products**	

	Type IA variation or Type IA immediate notification variation	25
	Type IB variation	40
	Type II variation	90
	Transfer of Marketing Authorization from one Marketing Authorization Holder to another	25
	Type IA group variation concerning one veterinary medicinal product	25 Euros for each Type IA variation
	Type IA group variation concerning more than one veterinary medicinal products of the same Marketing Authorization Holder ("annual report")	25 Euros for each Type IA variation plus 15 Euros for each veterinary medicinal product included in the application
	Type IA and/ or Type IB and/ or Type II variation for one veterinary medicinal product	The sum of the fees provided for the corresponding Types of variations
	Type IA and/ or Type IB and/ or Type II group variation concerning more than one veterinary medicinal products of the same Marketing Authorization Holder	25 Euros for each Type IA variation plus 15 Euros for each veterinary medicinal product included in the application
Exceptional marketing authorization	**For all veterinary medicinal products**	200

ANNEX II
[Regulation 3(1)(β)]

Fees for market authorization of veterinary medicinal products

MUTUAL RECOGNITION PROCEDURE AND DECENTRALIZED PROCEDURE
REPUBLIC OF CYPRUS AS CONCERNED MEMBER STATE

Type of application	Type of veterinary medicinal product	Fees for submitting the application in Euros (€)
New marketing authorization	**Full applications**	
	Full application for a marketing authorization according to Article 10 of the National Legislation or bibliographic application according to Article 13 of the National Legislation	500
	Extension of the marketing authorization of the above products (line extension or not)	350
	Simplified Procedure Applications	
	Application for a marketing authorization according to Article 12 of the National Legislation (essentially similar veterinary products – assent or expiration of the period of exclusiveness of the data)	400
	Extension of the marketing authorization of the above products (line extension or not)	350
Renewal of a market authorization	**For all veterinary medicinal products**	350
Variation of the market authorization	**For all veterinary medicinal products**	
	Type IA Variation or Type IA immediate notification variation	50
	Type IB variation	75

	Type II Variation	150
	Type IA group variation concerning one veterinary medicinal product	50 Euros for each Type IA variation
	Type IA group variation concerning more than one veterinary medicinal products of the same Marketing Authorization Holder ("annual report")	50 Euros for each Type IA variation plus 15 Euros for each veterinary medicinal product included in the application
	Type IA and/ or Type IB and/ or Type II variation for one veterinary medicinal product	The sum of the fees provided for the corresponding Types of variations
Variations according to the procedure of Article 20, Regulation EU/1234/2008	Type IB and/ or Type II group variation concerning more than one veterinary medicinal products	The sum of the fees provided for the corresponding Types of variations with the republic of Cyprus as Concerned member State plus 50 Euros for each veterinary medicinal product included in the application

ANEX III

[Regulation 3(1)(γ)]

Fees for market authorizations of veterinary medicinal products

MUTUAL RECOGNITION PROCEDURE AND DECENTRALIZED PROCEDURE REPUBLIC OF CYPRUS AS REFERENCE MEMBER STATE

Type of application	Type of veterinary medicinal product	Fees for submitting the application in Euros (€)
New marketing authorization	**Full applications**	
	Full application for a marketing authorization according to Article 10 of the National Legislation or bibliographic application according to Article 13 of the National Legislation	30.000
	Extension of the marketing authorization of the above products (line extension or not)	20.000
	Simplified Procedure Applications	
	Application for a marketing authorization according to Article 12 of the National Legislation (Essentially similar veterinary medicinal products – assent or expiration of the period of exclusiveness of the data)	20.000
	Extension of the market authorization of the above products (line extension or not)	12.000
Renewal of the marketing authorization	**For all veterinary medicinal products**	8.000
Variation of the marketing authorization	**For all veterinary medicinal products**	
	Type IA Variation or Type IA immediate notification variation	500
	Type IB variation	600

	Type II Variation	4.000
	Type IA group variation concerning one veterinary medicinal product	500 Euros for each Type IA variation
	Type IA group variation concerning more than one veterinary medicinal products of the same Marketing Authorization Holder ("annual report")	500 Euros for each Type IA variation plus 50 Euros for each veterinary medicinal product included in the application
Variations according to the procedure of Article 20, Regulation EU/1234/2008	Type IA and/ or Type IB and/ or Type II group variation concerning more than one veterinary medicinal products of the same Marketing Authorization Holder	The sum of the fees provided for the corresponding Types of variation with the Republic of Cyprus as concerned member state plus 50 Euros for each veterinary medicinal product included in the application

ANNEX IV

[Regulation 3(1)(δ)]

Fees for homeopathetic veterinary medicinal products

	Type of application	Fees for submitting the application in Euros (€)
1	Registration of an homeopathetic veterinary medicinal product according to the simplified procedure for registration	200
2	Renewal of the registration of an homeopathetic veterinary medicinal product	150
3	Type IA variation	25
4	Type IB variation	40
5	Type II variation	90

ANNEX V

[Regulation 3(1)(ε)]

Fees for parallel distribution of veterinary medicinal products

	Type of application	Fees for submitting the application in Euros (€)
1	Issue of an authorization for parallel distribution	500
2	Renewal of an authorization for parallel distribution	300

ANNEX VI
(Regulation 3(1)(στ))

Fees for wholesale distribution, manufacture authorization and authorization for imports of veterinary medicinal products from third countries, manufacture authorizations for medicated feeding stuffs and intermediate products, distribution authorizations and import authorizations for medicated feeding stuffs from third countries and the inspections that take place in the scope of examining these applications.

1. The amount of three thousand Euros (€ 3.000) should be paid with the application for issuing or renewing an authorization for full manufacture of veterinary medicinal products. This amount corresponds to one pharmaceutical form. For each extra pharmaceutical form, an extra amount of three thousand Euros (€ 3.000) is submitted.

2. The amount of two thousand Euros (€ 2.000) should be paid with the application for issuing or renewing an authorization for partial manufacture of veterinary medicinal products and includes only the packaging of the veterinary medicinal products.

3. The amount of one thousand and five hundred Euros (€ 1.500) should be paid with the application for issuing or renewing an authorization for import of veterinary medicinal products from third countries.

4. The amount of five hundred Euros (€ 500) should be paid for the inspection of the manufacturer for the issue or renewal of the authorization for manufacture of veterinary medicinal products or the variation of the manufacturing authorization by adding a new pharmaceutical form or a new premise.

5. The amount of one thousand and five hundred Euros (€ 1.500) should be paid for an inspection of a manufacturer abroad during the examination of an application for import of veterinary medicinal products. The charges for the transfer of the inspectors abroad are also added on this amount.

6. The amount of three hundred Euros (€ 3.000) should be paid for an inspection of a manufacturer for partial manufacture which includes only packaging, or an inspection concerning variation of the manufacturing authorization by adding a new premise.

7. The amount of seven hundred and fifty Euros (€ 750) should be paid with the application for issuing an authorization for wholesale.

8. The amount of six hundred Euros (€ 600) should be paid with the application for renewal of a wholesale authorization.

9. The amount of two hundred Euros (€ 200) should be paid for an auditing of the application for issuing a wholesale authorization.

10. The amount of seven hundred Euros (€ 700) should be paid with the application for issuing an authorization for manufacture of medicated feeding stuffs.

11. The amount of five hundred Euros (€ 500) should be paid for the inspection of a manufacturer of medicated feeding stuffs or intermediate products, for issue or renewal of the manufacture authorization of medicated feeding stuffs or intermediate products.

12. The amount of three hundred and fifty Euros (€ 350) should be paid with the application for renewal of the manufacture authorization of feeding stuffs.

13. The amount of four hundred Euros (€ 400) should be paid with the application for issue of an authorization for distribution of medicated feeding stuffs.

14. The amount of two hundred and fifty Euros (€ 250) should be paid for an issue of distribution authorization of medicated feeding stuffs.

15. The amount of four hundred Euros (€ 400) should be paid with the application for renewal of a distribution authorization for medicated feeding stuffs.

16. The amount of seven hundred Euros (€ 700) should be paid with the application for issue or renewal of a manufacturing authorization for an intermediate product.

17. The amount of three hundred and fifty Euros (€ 350) should be paid with the application for renewal of a manufacturing authorization for an intermediate product.

18. The amount of one thousand Euros (€ 1.000) should be paid with the application for issue of an authorization for import of medicated feeding stuffs from third countries.

19. The amount of one hundred Euros (€ 100) should be paid with the application for examination for obtaining a wholesaler authorization.

ANNEX VII

[Regulation 3(2)]

Other fees to be submitted, according to the provisions of the Law.

1. The amount of one hundred Euros (€ 100) should be paid with the application for issue of an authorization for clinical trials of veterinary products.

2. The amount of two hundred (€ 200) should be paid for the issue of an authorization for clinical trials of veterinary medicinal products.

3. The amount of one hundred and fifty Euros (€ 150) should be paid with the application for engaging in the activities of a qualified person.

4. The amount of three hundred Euros (€ 300) should be paid with the submission of a three year Periodic Safety Update Report (PSUR) by the Marketing Authorization Holder.

5. The amount of twenty Euros (€ 20) should be paid for issue of any certificate, according to the provisions of the Law.