Applicable Fees for different types of procedures

The medicines for human use (quality, supply and price control) law Decree by virtue of article 103A

Applicable Fees for Marketing Authorisations of Human Medicinal Products

National Marketing Authorisations

Initial marketing	Legal type of application	Application fees Euros (€)	Fees for issuing a license
authorisation	FULL APPLICATIONS		
	Complete application for the granting of a marketing authorization pursuant to Article 8(3) of the Directive 2001/83/EC or bibliographical application pursuant to Article 10(a). Application for the granting of a marketing authorization pursuant to Article10(b) (fixed combination applications)	1024	0
	Extensions (Annex I of Regulation (EC) No 1234/2008) of complete or bibliographical authorisations.	682	0
	ABRIDGED APPLICATIONS		
	Application for the granting of a marketing authorisation pursuant to Article10(1) (generic applications).	682	0

	Application for the granting of a		
	marketing authorisation pursuant to		
	Article10(3) (hybrid applications).		
	Article 10(3) (hybrid applications).		
	Application for the granting of a		
	marketing authorisation pursuant to		
	Article10(c) (informed consent		
	applications).		
	Application for the granting of a		
	marketing authorisation pursuant to		
	Article10(4) (similar biological		
	applications).		
	Extensions (Annex I of Regulation (EC)		
	No 1234/2008) of generic, hybrid,	540	2
	informed consent and similar biological	512	0
	applications.		
Renewal of a			
marketing	For all legal types of applications	340	0
authorisation			
Variation of			
marketing	For all legal types of applications		
authorisation			
	Tura I Mariatian	47	
	Type I Variation	17	0
		51	0
	Type II Variation	υı	U
Exceptional			
(Special)	Applications based on article 126a of the		
marketing	Directive 2001/83/EC	307	0
authorisation			
aunonsanon			
Renewal of	Renewal of applications based on article	170	0
			v

Exceptional	126a of the Directive 2001/83/EC	
(special)		
marketing		
authorisation		

DECENTRASILED AND MUTUAL RECOGNITION PROCEDURES WITH CYPRUS AS A CONCENRED MEMBER STATE (CMS)

	Legal type of application	Application fees	Fees for issuing a licence
		Euros (€)	
Initial marketing authorisation	FULL APPLICATIONS		
	Complete application for the granting		
	of a marketing authorisation pursuant		
	to Article 8(3) of Directive		
	2001/83/EC, or bibliographical		
	application pursuant to Article 10(a).	1708	0
	Application for the granting of a		
	marketing authorisation pursuant to		
	Article10(b) (fixed combination		
	applications).		
	Extensions (Annex I of Regulation		
	(EC) No 1234/2008) of complete or	1024	0
	bibliographical authorisations.	1024	0
	ABRIDGED APPLICATIONS		
	Application for the granting of a		
	marketing authorisation pursuant to	1024	0
	Article10(1) (generic applications).		

	Application for the granting of a		,
	Application for the granting of a		
	marketing authorisation pursuant to		
	Article10(3) (hybrid applications).		
	Application for the granting of a		
	marketing authorisation pursuant to		
	Article10(c) (informed consent		
	applications).		
	Application for the granting of a		
	marketing authorisation pursuant to		
	Article10(4) (similar biological		
	applications).		
	Extensions (Annex I of Regulation		
	(EC) No 1234/2008) of generic,		2
	hybrid, informed consent and similar	682	0
	biological applications.		
Renewal of a			
marketing	For all legal type of applications	1024	0
authorisation			
Variation of			
marketing	For all legal type of applications		
authorisation			
authorisation			
	Type I Variation	85	0
	Type II Variation	341	0

DECENTRALISED AND MUTUAL RECOGNITION PROCEDURE WITH CYPRUS AS A REFERENCE MEMBER STATE (RMS)

Initial marketing authorisation	Legal type of application FULL APPLICATIONS	Application fees Euros (€)	Fees for issuing a licence
	Complete application for the granting of a marketing authorisation pursuant to Article 8(3) of Directive 2001/83/EC, or bibliographical application pursuant to Article 10(a). Application for the granting of a marketing authorisation pursuant to Article10(b) (fixed combination applications).	27320	0
	Extensions (Annex I of Regulation (EC) No 1234/2008) of complete or bibliographical authorisations.	17080	0
	ABRIDGED APPLICATIONS		
	Application for the granting of a marketing authorisation pursuant to Article10(1) (generic applications).	17080	0

	Application for the granting of a marketing authorisation pursuant to Article10(3) (hybrid applications).		
	Application for the granting of a marketing authorisation pursuant to Article10(c) (informed consent applications).		
	Application for the granting of a marketing authorisation pursuant to Article10(4) (similar biological applications).		
	Extensions (Annex I of Regulation (EC) No 1234/2008) of generic, hybrid, informed consent and similar biological applications.	10240	0
Renewal of marketing authorisation	For all legal type of applications	6820	0
Variation of marketing authorisation	For all legal type of applications	341	0
	Type II Variation	341	0

Fees for homeopathic medicinal products

	Application Type	Application	Registration
		fees	fees
		Euros (€)	
1.	Registration of a homeopathic medicinal product pursuant to the simplified registration procedure. (Article 14 of Directive 2001/83/EC)	170	0
2.	Renewal of the registration of a homeopathic medicinal product	102	0

	Application type	Application	Registration
	Application type	fees	fees
		Euros (€)	
	REGISTRATION VIA THE NATIONAL		
A.	PROCEDURE		
4	Application for registration of a	690	0
1.	traditional herbal medicinal product	682	0
2.	Renewal of the registration of a	340	0
Ζ.	traditional herbal medicinal product	340	0
3.	Variation of the registration of a		
0.	traditional herbal medicinal product		
	Type I Variation	17	0
	Type II Variation	51	0
	REGISTRATION VIA THE MUTUAL		
	RECOGNITION PROCEDURE AND		
В.	DECENTRALISED PROCEDURE		
υ.	WITH CYPRUS AS A CONCERNED		
	MEMBER STATE		
	Application for registration of a		
1.	traditional herbal medicinal product	1024	0
	Renewal of the registration of a		
2.	traditional herbal medicinal product	1024	0
	· · ·		
•	Variation of the registration of a		
3.	traditional herbal medicinal product		

Fees for herbal medicinal products

	Type I Variation	85	0
	Type II Variation	341	0
	REGISTRATION VIA THE MUTUAL		
	RECOGNITION PROCEDURE AND		
C.	DECENTRALISED PROCEDURE		
	WITH CYPRUS AS A REFERENCE		
	MEMBER STATE		
1.	Application for registration of a	17080	0
1.	traditional herbal medicinal product	17000	0
2.	Renewal of the registration of a	6820	0
۷.	traditional herbal medicinal product	0020	U
3.	Variation of the registration of a		
0.	traditional herbal medicinal product		
	Type I Variation	341	0
	Type II Variation	3410	0

Fees for parallel import licence

	Application type	Application fees	Fees for issuing a licence
		€	
1	Parallel import licence	340	0
2	Renewal of a Parallel import licence	170	0