

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

	Legal type of application	Application fees	Fees for issuing a license
		Euros (€)	
Initial marketing 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 Article 10(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 Article 10(1) (generic applications).	682	0

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

Exceptional (special) marketing authorisation	126a of the Directive 2001/83/EC		
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**DECENTRALISED AND MUTUAL RECOGNITION PROCEDURES
WITH CYPRUS AS A CONCERNED 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). Application for the granting of a marketing authorisation pursuant to Article 10(b) (fixed combination applications).	1708	0
	Extensions (Annex I of Regulation (EC) No 1234/2008) of complete or bibliographical authorisations.	1024	0
	ABRIDGED APPLICATIONS		
	Application for the granting of a marketing authorisation pursuant to Article 10(1) (generic applications).	1024	0

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

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

	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). Application for the granting of a marketing authorisation pursuant to Article 10(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 Article 10(1) (generic applications).	17080	0

	<p>Application for the granting of a marketing authorisation pursuant to Article10(3) (hybrid applications).</p> <p>Application for the granting of a marketing authorisation pursuant to Article10(c) (informed consent applications).</p> <p>Application for the granting of a marketing authorisation pursuant to Article10(4) (similar biological applications).</p>		
	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		
	Type I Variation	341	0
	Type II Variation	3410	0

Fees for homeopathic medicinal products

	Application Type	Application fees	Registration 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

Fees for herbal medicinal products

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

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