MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

AEMPS* Fees 2017

(Valid from 29th June 2017) *Spanish Agency of Medicines and Medical Devices

Law 3/2017, dated 27 June 2017, of the National General Budget for 2017, article 64.One

(Boletín Oficial del Estado (BOE), nº153, 28 June 2017)

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
GROUP I.	**MEDICINES FOR HUMAN USE.**	
	Evaluation, authorisation and registration of new medicines	
1.1	Fee for the evaluation, authorisation and ***registration*** of a new medicine for human use (application in accordance with article 17, with the exception of the provision in 17.3)	**20.941,80**
1.2	Fee for the evaluation, authorisation and ***registration*** of a new generic medicine for human use (application in accordance with article 17.3)	**8.518,56**
1.3	Fee for the evaluation, authorisation and registration of a new medicinal gas	**8.518,56**
	Change of ownership of a medicine for human use	
1.4	Fee for changing the ownership of a marketing authorisation for a medicine for human use, or for changing the owner's representative.	**711,60**
	Evaluation, authorisation and registration of a variation of the marketing authorisation of a medicine for human use	
1.5	Fee for the variation of a marketing authorisation for medicines for human use, classified as of «major importance» Type II	**7.193,47**
1.6	Fee for the variation of a marketing authorisation for medicines for human use, classified as Type IB	**1.261,71**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
1.7	Fee for the variation of a marketing authorisation for medicines for human use, classified as type IA (including those of type IA with immediate notification)	**731,66**
	Renewalapplications	
1.8	Fee for the renewal application for a medicine for human use	**2.366,14**
	Annual fees for authorised medicines	
1.9	Annual fee for the maintenance of an already-authorised medicine for human use	**377,44**
	Fees for parallel imported medicinal products	
1.10	Fee for the authorisation procedure for a parallel imported medicine for human use	**914,50**
1.11	Fee for the variation for a parallel imported medicine for human use	**370,15**
1.12	Fee for the renewal for a parallel imported medicine for human use	**370,15**
1.13	Fee for the notification of an imported medicine for human use	**362,63**
	Fees for the batch release of vaccines, blood products and bulks	
1.14	Fee for issuing an European certification for the batch release of vaccines and blood products for human use when the batch-analysis of a medicine is required	**1.224,12**
1.15	Fee for the batch release of blood products and vaccines in accordance with articles 41.4 and 43.3 of Royal Decree 1345/2007, of 11th October	
1.15.a)	a) each individual application	**102,01**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
1.15.b)	b) between 6 and 10 applications/year (per year)	**510,05**
1.15.c)	c) between 11 and 40 applications/year (per year)	**1.530,15**
1.15.d)	d) between 41 and 160 applications/year (per year)	**3.570,35**
1.15.e)	e) for more than 160 applications/year (per year)	**5.100,50**
1.16	Fee for issuing an European certification for the batch release of vaccines and blood products for human use when a bulk-analysis is required (by bulk)	**342,75**
	Fees for the evaluation of galenic innovations	
1.17	Fee for the evaluation of an application for a galenic innovation	**993,88**
	Feesforexporting	
1.18	Authorisation to export narcotic and psychotropic medicines to EU countries and third countries	**173,42**
	Miscellaneous	
1.19	Fee for the activities outlined in section 6 of article 11	**370,15**
1.20	Fee for reserving a slot to act as the Reference Member State in a Decentralised or Mutual Recognition Procedure	**765,08**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
GROUP II.	**ALLERGEN PRODUCTS**	
	Evaluation, authorisation and registration of a new allergen product for diagnostic use	
2.1	Fee for processing in Spain	**869,54**
	Change of ownership of an allergen product for diagnostic use	
2.2	Fee for changing the ownership of a marketing authorisation for an allergen productfor diagnostic use	**477,18**
	Evaluation, authorisation and registration of a variation of an allergen product for diagnostic use	
2.3	Fee for the variation of a marketing authorisation for allergen products classified as of «major importance» Type II	**507,77**
2.4	Fee for the variation of a marketing authorisation for allergen products classified as Type IB	**89,07**
2.5	Fee for the variation of a marketing authorisation for allergen products classified as type IA (including those of type IA with immediate notification)	**51,65**
	Renewalapplications	
2.6	Fee for the renewal application for an allergen product for diagnostic use	**310,45**
	Annual fees for allergen products	
2.7	Annual fee for the maintenance for an already-authorised allergen product for diagnostic use	**377,44**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
	Fee for bulk release	
2.8	Fee for bulk authorisation (by bulk)	**620,92**
GROUP III.	**HERBAL MEDICINAL PRODUCTS**	
	Evaluation, authorisation and registration of a new traditional herbal medicinal product	
3.1	Fee for the simplified procedure in Spain	**2.208,81**
	Evaluation, authorisation and registration of a variation of a traditional herbal medicinal product	
3.2	Fee for the variation of a marketing authorisation for a traditional herbal medicinal product	**342,37**
	Evaluation, authorisation and registration of a new herbal medicinal product for human use by a well-established use procedure	
3.3	Fee for the national procedure, except for 3.1	**8.518,56**
	Change of ownership of herbal medicinal products	
3.4	Fee for changing the ownership of a marketing authorisation for a traditional herbal medicinal product or a herbal medicinal product authorised by a well-established use procedure	**711,60**
	Evaluation, authorisation and registration of a variation of a herbal medicinal product	
3.5	Fee for the variation of a marketing authorisation for a herbal medicinal product for human use classified as of «major importance» Type II	**1.261,71**
3.6	Fee for the variation of a marketing authorisation for a herbal medicinal product for human use classified as Type IB	**563,25**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
3.7	Fee for the variation of a marketing authorisation for a herbal medicinal product for human use classified as Type IA (including those of type IA with immediate notification)	**321,03**
	Renewalapplications	
3.8	Fee for the renewal application for a traditional herbal medicinal product	**310,45**
3.9	Fee for the renewal application for a herbal medicinal product authorised by a well-established use	**1.538,18**
	Annual fees for authorised herbal medicinal products	
3.10	Annual fee for the maintenance for a traditional herbal medicinal product	**377,44**
3.11	Annual fee for the maintenance for a herbal medicinal product authorised by a well-established use	**377,44**
GROUP IV.	**HOMEOPATHIC MEDICINES FOR HUMAN AND VETERINARY USE**	
	Evaluation, authorisation and registration of a new homeopathic medicine without approved therapeutic indications	
	Fee for the national procedure	
4.1	- A single stock	**602,66**
4.2	- Between two and five stocks	**753,31**
4.3	- More thansix stocks	**941,64**
	Evaluation, authorisation and registration of a variation of the marketing authorisation of a homeopathic medicine without approved therapeutic indications	

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
4.4	Fee for the variation of the marketing authorisation of a homeopathic medicine without approved therapeutic indications	**332,30**
	Evaluation, authorisation and registration of a new homeopathic medicine with approved therapeutic indications	
4.5	Fee for the national procedure	**8.518,56**
	Change of ownership of a homeopathic medicine with or without approved therapeutic indications	
4.6	Fee for transfer of marketing authorisation for a homeopathic medicine with or without approved therapeutic indications or for changing the owner's representative	**711,60**
	Evaluation, authorisation and registration of a variation of the marketing authorisation of a homeopathic medicine with approved therapeutic indications	
4.7	Fee for the variation of a marketing authorisation for a homeopathic medicine with approved therapeutic indications classified as of «major importance» Type II	**1.261,71**
4.8	Fee for the variation of a marketing authorisation for a homeopathic medicine with approved therapeutic indications classified as Type IB	**563,25**
4.9	Fee for the variation of a marketing authorisation for a homeopathic medicine with approved therapeutic indications classified as Type IA (including those of type IA with immediate notification)	**321,03**
	Renewalapplications	
4.10	Fee for the renewal application for a homeopathic medicine without approved therapeutic indications	**310,45**
4.11	Fee for the renewal application for a homeopathic medicine with approved therapeutic indications	**1.538,18**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
	Annual fees for authorised homeopathic medicines	
4.12	Annual fee for the maintenance of an already-authorised homeopathic medicine without approved therapeutic indications	**91,81**
4.13	Annual fee for the maintenance of an already-authorised homeopathic medicine for human use with approved therapeutic indications	**377,44**
GROUP V.	**CLINICAL RESEARCH**	
5.1	Fee for the evaluation of a first clinical trial with medicines that are not authorised in a country that belongs to the International Conference on Harmonisation (ICH) with active substances or combinations of active substances that are not authorised in Spain	**4.284,42**
5.2	Fee for the evaluation of:	
	a) A clinical trial with a medicine that is authorised in a country other than Spain that belongs to the International Conference on Harmonisation (ICH)	
	b) Clinical trials with medicines that are not authorised in any country belonging to the International Conference on Harmonisation (ICH), following a first clinical trial included in the category 5.1	
	c) Clinical trials with the characteristics outlined in 5.1 in the event of resubmission when the outcome of the first application was a withdrawal of the application or was refused	
	d) Clinical trials with a medicine that is not authorised in a country belonging to the International Conference on Harmonisation (ICH), with active substances that are authorised in Spain	**408,04**
5.3	Fee for the evaluation of:	

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
	a) Clinical trials with medicines authorised in Spain, irrespective of their specific labelling for the trial	**113,42**
	b) Clinical trials whose sponsor is a researcher or group of researchers and in which a Pharmacy Service is responsible for preparing or blinding the medicines under investigation	
5.4	Procedure for classifying a veterinary medicine that is not authorised in Spain as investigational medicinal product	**280,95**
5.5	Fee for the veterinary clinical trials procedure	**113,42**
GROUP VI.	**PHARMACEUTICAL LABORATORIES, MANUFACTURERS, IMPORTERS OR DISTRIBUTORS OF ACTIVE SUBSTANCES OR OTHER ENTITIES THAT CARRY OUT ACTIVITIES WITH MEDICINES OR ACTIVE SUBSTANCES**	
6.1	Authorisation of a new pharmaceutical laboratory	**5.975,52**
6.2	Minor changes to a pharmaceutical laboratory authorisation	**332,30**
6.3 a)	Major changes to a pharmaceutical laboratory authorisation, when the inspection activities do not include an inspection visit	**3.935,32**
6.3 b)	Major changes to a pharmaceutical laboratory authorisation, when the inspection activities include an inspection visit	**5.975,52**
6.4 a)	Individual inspection activities in Spain, unless a complaint has been made or it is requested by a representative association of consumers	**5.055,02**
6.4 b)	Individual inspection activities in third countries, unless a complaint has been made or it is requested by a representative association of consumers	**11.017,08**
6.4 c)	Individual inspection activities, in third countries, non-mandatory, requested by the interested party	**20.402,00**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
6.5	Authorisation for the manufacturing process of medicines approved in other countries but not authorised in Spain	649,65
6.6	Exceptional manufacturing authorisation by a third party of medicines for human and/or veterinary use	332,30
6.7	Authorisation and/or certification for medicines warehouses under customs control or supervision	1.326,13
6.8	Decision to authorise the cultivation of plants that can be used for manufacturing narcotics and psychotropic medicines	612,06
6.9	Initial registration, notification of mandatory changes or annual updating of the registry of manufacturers, importers or distributors of active substances	816,08
6.10	Registration of Brokers of medicines for human use	255,03
GROUP VII.	**CERTIFICATIONS AND REPORTS**	
7.1	Fee for issuing a certificate	143,28
7.2	Fee for scientific advice for medicines, including multidisciplinary questions on (a) quality, safety and clinical development, or (b) quality and clinical development or (c) safety and clinical development, or (d) presubmission advice	4.266,63
7.3	Fee for scientific advice for medicines, including questions about (a) clinical development, or (b) quality and safety or (c) quality and bioequivalence studies in the case of generic medicines	3.092,05
7.4	Fee for scientific advice for medicines, including questions about (a) quality or (b) safety or (c) bioequivalence studies in the case of generic medicines	2.042,97
7.5	Fee for follow-up advice in those cases included in subsection 7.2	2.042,97

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
7.6	Fee for follow-up advice in those cases included in subsection 7.3	**1.546,04**
7.7	Fee for follow-up advice in those cases included in subsection 7.4	**993,88**
7.8	Fee for advice on classifying variations that have not been classified, in accordance with article 5, and for the grouping of variations, in accordance with article 7 of European Commission (EC) Regulation 1234/2008	**496,93**
7.9	Fee for scientific advice on medicines for paediatric use in any of the cases included in the above subsections	**207,06**
7.10	Scientific/technical advice on the design of facilities and manufacturing processes in accordance with good manufacturing practices	**496,93**
GROUP VIII.	**MEDICAL DEVICES, COSMETICS AND PERSONAL CARE PRODUCTS**	
8.1	Procedure of special declaration for cosmetics products	**492,78**
8.2	Procedure of individually registering and authorising personal care products and disinfectants	**492,78**
8.3	Procedure for registering and recording medical devices	**102,01**
8.4	Procedure for modifying and validating personal care products and disinfectants	**171,72**
8.5	ProcedureforCertificateissuing	**149,30**
8.6	Procedure of verification and control of the statement of compliance for the manufacturing of cosmetics and personal care products	**724,25**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
8.7	Procedure of verification and control of the statement of compliance for the importation activity of cosmetics and personal care products	**373,33**
8.8	Procedure of verification and control of the statement of compliance for modification in the manufacture activity of cosmetics and personal care products	**373,33**
8.9	Procedure of verification and control of the statement of compliance for modification in the importation activity of cosmetics and personal care products	**171,72**
8.10	Individual inspection activities to verify the statement of compliance	**724,25**
8.11	Procedure of authorisation of confidentiality of cosmetic ingredients	**492,78**
8.12	Procedure of preliminary operating licence for medical devices and disinfectants: manufacturing establishment, systems and procedure packs manufacturing establishment	**724,25**
8.13	Procedure of preliminary operating licence for medical devices and disinfectants: import establishment	**373,33**
8.14	Procedure of modification of preliminary operating licence for medical devices and disinfectant establishments in relation to facilities location: manufacturing facilities, Systems and procedure packs manufacturing facilities	**724,25**
8.15	Procedure of modification of preliminary operating licence of medical devices and disinfectant facilities in relation to facilities location: import establishment	**373,33**
8.16	Procedure of modification of preliminary operating licence procedure for medical devices and disinfectant establishments	**171,72**
8.17	Procedure of revalidation the licence of medical devices and disinfectant establishments: manufacturing establishment	**522,64**
8.18	Procedure of revalidation of the licence of medical devices and disinfectant establishments: importing establishment	**321,06**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
8.19	Authorisation for clinical research of medical devices	**816,08**
8.20	Assessment report on medicinal products incorporated into medical devices	**1.493,29**
8.21	Assessment of «CE» mark certification files for medical devices within the same family according to full quality assurance system procedure	**2.484,96**
8.22	Assessment of «CE» mark certification files for medical devices according to EC type examination procedure, combined with production quality assurance, EC verification or product quality assurance	**895,97**
8.23	Assessment of «CE» mark certification files for medical devices within the same family, through EC declaration of conformity combined with production quality assurance, EC verification or product quality assurance	**746,66**
8.24	Verification of products and batches of products	**232,47**
8.25	Assessment of «CE» mark certification files for medical devices according to EC design examination	**1.642,63**
8.26	Initial audit in accordance with full quality assurance system	**3.264,32**
8.27	Initial audit in accordance with production quality assurance	**2.713,47**
8.28	Initial audit in accordance with product quality assurance	**2.175,87**
8.29	Follow-up audits and certification extension audits	**2.175,87**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
8.30	Audits on additional premises and repeat audits	**1.088,45**
8.31	Change to administrative details on «CE» mark certification	**149,30**
8.32	Extensions to «CE» mark certifications	**149,30**
8.33	Procedure of modifications of medical devices	**61,21**
GROUP IX.	**VETERINARY MEDICINAL PRODUCTS (VMPs)**	
9.1	Fee for applying for market authorisation for a veterinary medicinal product (VMP), except for applications outlined in article 17.3	**10.470,89**
9.2	Fee for applying for market authorisation for a generic VMP (file issued in accordance with article 17.3).	**4.259,27**
9.3	Fee for transfer of a marketing authorisation of a VMP, or for changing the local representative	**711,60**
9.4	Fee for the procedure of modifying the authorisation for VMP, classified as «major importance» Type II	**3.596,74**
9.5	Fee for the procedure of modifying the authorisation for VMP, classified as Type IB.	**1.236,97**
9.6	Fee for the procedure of modifying the authorisation for VMP, classified as type IA (including those type IA with immediate notification)	**731,66**
9.7	Fee for the authorisation of the renewal procedure for a VMP	**2.366,14**

TYPE	DESCRIPTION	Update 2017 (Application of coefficient 1.01) EUROS
9.8	Annual single fee for declaring an intention of commercialisation of an already-authorised VMP	**121,40**
9.9	Fee for the authorisation procedure for the «parallel importing» of a VMP	**746,32**
9.10	Fee for assessment of the six-monthly safety report of a VMP, whether or not the product is registered in Spain	**386,54**
9.11	Fee for assessment of the annual safety report of a veterinary medicine, whether or not the product is registered in Spain	**765,42**
9.12	Fee for assessment of the three-yearly or longer safety report of a VMP, whether or not the product is registered in Spain	**2.296,26**
9.13	Fee for issuing European certification for the formal batch release of an immunological VMP in accordance with article 81 of Directive 2001/82/EC	**342,75**
9.14	Fee for issuing European certification for the formal batch release of an immunological VMP in accordance with article 82 of Directive 2001/82/EC	**1.224,12**
9.15	Fee for reserving a slot for Spain to act as the Reference Member State in a Decentralised or Mutual Recognition procedure	**408,04**