



Fees in relation to marketing authorizations in Luxembourg

RGD du 14.6.2013 modifiant le RGD du 24.12.1993 fixant les droits dus pour la mise sur le marché des médicaments, published in the Official Journal A N°109 from June 28th 2013.

Loi du 19 décembre 2014 relative à la mise en œuvre du paquet d'avenir publié au Mémorial A N° 257 du 24 décembre 2014)¹, qui a introduit une série de nouvelles taxes en matière de médicaments humains et vétérinaires applicables à partir du 1^{er} janvier 2015.

National applications if a marketing authorization in another EEC member-state already exists:	600 €	To be paid prior to the application
Application via the mutual recognition and decentralized procedure	600 €	To be paid prior to the application
Annual fee to maintain marketing authorizations (not applicable for centrally authorized products)	100 €	Annually, per pharmaceutical form and per strength
Application for a renewal of a marketing authorization (not applicable for new MA granted after 2022)	600 €	To be paid prior to the application
Variation Type VNRA (previously type I)	0 €	
Variation Type VRA (previously type II) (per variation)	150 €	To be paid prior to the application
Application for release of advertisement on medicinal products	500 €	To be paid prior to the application
Application for a clinical trial	1 000 €	To be paid prior to the application
Application for a substantial amendment of a clinical trial	1 000 €	To be paid prior to the application

These fees are the same for all kinds of applications (new active substances, abridged applications....)

The fee has to be paid by transfer to the following account:

Please be advised that as **of January 1st 2024**, the account number for the payment of fees has changed; the new account to be credited is the following:

IBAN LU36 0019 5955 4436 2000

SWIFT/BIC: BCEELULL

SPUERKEESS Banque et Caisse d'Epargne de l'Etat, Luxembourg

The holder of the account is :

Administration de l'Enregistrement, des Domaines et de la TVA, Amendes et Recouvrements,
1-3 avenue Guillaume,
L-1651 Luxembourg

For payments prior to the application, a proof of payment, **indicating the procedure number** has to be added to the dossier.

Please note that we are not able to accept chèques.