



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)

(La 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, a introduit une série de nouvelles taxes en matière de médicaments 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
National application if no marketing authorization in any EEC member-state exists:	12 500 €	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	100 €	Annually
Application for a renewal of a marketing authorization	600 €	To be paid prior to the application
a minor variation Type IA/IB	50 €	Semi-annually
a major variation Type II	150 €	Semi-annually
a worksharing or grouped variation	Per variation included	Semi-annually
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:

- **Postal account no. IBAN LU31 1111 0077 3370 0000**
(SWIFT CODE: CCPL LULL)
Chèques Postaux – L-1010 Luxembourg

In case you have problems to transfer the requested amount to the above mentioned account, you may use the following account

- **Bank account no. IBAN LU16 0019 1002 4423 5000**
(SWIFT CODE: BCEE LULL)
Banque et Caisse d'Épargne de l'État – Place de Metz – L-2954 Luxembourg

The holder of the accounts is the 'Administration de l'Enregistrement et des Domaines' – B.P.31 – L-2010 Luxembourg.

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

For payments concerning clinical trials please indicate the EudraCT number followed by Initial (for new applications) or SA"# (for substantial amendments)

For semi-annual and annual payments, always **indicate the payment reference** mentioned in our letter.

Please note that we are not able to accept cheques!