



## Fees in relation to marketing authorizations in Luxembourg

Legal basis :

- Loi du 11 avril 1983 portant réglementation de la mise sur le marché et de la publicité des médicaments, articles 9, 12 and 16 ;
- Règlement grand-ducal du 14 juin 2013 modifiant le règlement grand-ducal du 24 décembre 1993 fixant les droits dus pour la mise sur le marché des médicaments.

Procedure type	Amount	Payment modality
Marketing authorisation application via a national procedure (including line extensions)	12500 €	Amount per pharmaceutical form and strength, to be paid prior to the application, direct payment
Marketing authorisation application via the mutual recognition, repeat-use and decentralized procedure (including line extensions), with LU as CMS	600 €	Amount per pharmaceutical form and strength, to be paid prior to the application, direct payment
Annual fee to maintain marketing authorizations	100 €	Amount per pharmaceutical form and strength, to be paid annually, invoice is sent to applicant
Application for a renewal of a marketing authorization	600 €	Amount per pharmaceutical form and strength, to be paid prior to the application, direct payment
Application for a variation type IA/IB and MAH transfer	50 €	Payment is semi-annual, reminder letter is sent to applicant
Application for a variation type II	150 €	Payment is semi-annual, reminder letter is sent to applicant
Application for a worksharing or grouped variation	50/150 €, depending on the variations included	Payment is semi-annual, reminder letter is sent to applicant

### **Account:**

IMPORTANT: Please be advised that as of January 1<sup>st</sup>, 2024, the account number for the payment of fees has changed. The former account number will remain open with a transition period of 1 year.

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

Postal account no:	IBAN LU36 0019 5955 4436 2000
SWIFT/BIC:	BCEELULL
Name and address :	Banque et Caisse d'Epargne de l'Etat 1, Place de Metz, L-1930 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

### **How to pay**

For direct payments (initial applications), the applicant is requested to directly perform the transaction for each application, **with clear indication of the name and procedure number in the transaction.**

For all semi-annual payments (variations), the MAH will be contacted by post and is then requested to pay the fees, **indicating the payment reference** mentioned in the letter.

Please note that we are not able to accept cheques!

### **Proof of payment:**

For initial applications, a proof of payment indicating the product name and procedure number has to be **added to the eCTD dossier** sent via CESP (Module1 / 12form / lu).