



Fees in relation to marketing authorizations Luxembourg

Amounts to be paid:

<i>Procedure type</i>	<i>Amount (€)</i>	<i>Denominator</i>
Marketing authorisation application via a national procedure (including line extensions)	12500	per pharmaceutical form and strength
Marketing authorisation application via the mutual recognition, repeat-use and decentralized procedure (including line extensions), with LU as CMS	600	per pharmaceutical form and strength
Annual fee to maintain marketing authorizations	100	per pharmaceutical form and strength
Application for a renewal of a marketing authorization	600	per pharmaceutical form and strength
Application for a variation type IA/IB	50	per dossier submitted* (NEW!)
Application for a variation type II	150	per dossier submitted* (NEW!)
Application for a worksharing or grouped variation, if only type I variations included	50	per dossier submitted* (NEW!)
Application for a worksharing or grouped variation, if at least 1 type II variation included	150 €	per dossier submitted* (NEW!)

*i.e. even if more than one medicine, strength, or pharmaceutical form are concerned, or if more than one variations are included in one same dossier, this is considered 1 amount to be paid. 1 submitted dossier = 1 procedure number = 1 fee to be paid.

Bank account:

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

Bank 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*

Holder of the bank account: *Administration de l'Enregistrement, des Domaines et
de la TVA, Amendes et Recouvrements
1-3 avenue Guillaume
L-1651 Luxembourg*

Payment modality (NEW for variations!)

Since January 2025, the payments must be done **prior to submission of the dossier**. In the transaction's description, the **name of the product** as well as the **procedure number** must be clearly indicated.

A **proof-of-payment** must be sent with the respective initial sequence of the eCTD dossier (module1/12form/lu). There is no national template.

Transition period

A transition period will apply for variations and annual MA fees: MAHs or applicants can pay the 2025- fees semi-annually or annually. No invoice will be sent for required amount, the total amount to be paid needs to be calculated by the MAH/applicant based on the table above. Verification of the received amounts will be performed subsequently by the DPM.

References:

1 Loi du 11 avril 1983 portant réglementation de la mise sur le marché et de la publicité des médicaments.

2 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.