

Fees 2025 - Human medicinal products

Chapter 1 - Section 1 - Part 1 : Application for MA/registration, including line extensions (national)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	45.748,88 €	695,26 €
generic/informed consent application MAD	34.706,58 €	695,26 €
application MAD or registration herbal medicine		
1) conform monograph	27.112,36 €	695,26 €
2) non-conform monograph	45.748,88 €	695,26 €

If Belgium is acting as RMS : specific contribution (see infra).

Contribution per submitted dossier, regardless of the number of MADs.

* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 1 - Part 3 : Application for MA/registration, including line extensions (DCP/MRP/RUP, BE=RMS)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	66.431,28 €	695,26 €
generic/informed consent application MAD	54.233,19 €	695,26 €
application MAD or registration herbal medicine		
1) conform monograph	36.276,64 €	695,26 €
2) non-conform monograph	66.431,28 €	695,26 €

Contribution per submitted dossier, regardless of the number of MADs.

* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 1 - Part 2 : Application for MA/registration, including line extensions (DCP/MRP/RUP, BE=CMS)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	15.463,80 €	695,26 €
generic/informed consent application MAD	13.599,05 €	695,26 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	13.599,05 €	695,26 €

Contribution per submitted dossier, regardless of the number of MADs.

* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.

+ Chapter 3

a) Delayed closing of the dossier at request of the applicant 1.061,12 €

Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s)

1.448,07 €

Chapter 1 - Section 2 - Part 1 : Renewal (national)

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Renewal	8.121,36 €	695,26 €
Renewal herbal medicine	5.368,36 €	695,26 €

If Belgium is acting as **RMS : specific contribution** (see infra).

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 2 - Part 3 : Renewal (MRP, BE = RMS)

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Renewal	16.319,99 €	695,26 €
Renewal herbal medicine	10.936,01 €	695,26 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

Chapter 1 - Section 2 - Part 2 : Renewal (MRP, BE = CMS)

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Renewal	1.264,14 €	695,26 €
Renewal herbal medicine	1.548,31 €	695,26 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs.

* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.

+ Chapter 3

a) Delayed closing of the dossier at request of the applicant

729,21 €

Chapter 1 - Section 3 - Part 1 : National variations

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a) 1) Type IA variations	676,84 €	676,84 € (+ 201,16 €/additional brand)		676,84 €
a) 2) Type IA variations herbal medicine	1.066,47 €	1.066,47 € (+ 201,16 €/additional brand)		695,26 €
Part 4 administrative variations	747,34 €	747,34 € (+ 208,70 €/additional brand)		695,26 €
b) 1) Type IB variations	1.255,07 €	1.255,07 € (+ 201,16 €/additional brand)		695,26 €
b) 1) Type IB variations herbal medicine	1.997,59 €	1.997,59 € (+ 201,16 €/additional brand)		695,26 €
c) Type II variations: analytical				
variations regarding the analytical part ****	10.048,35 €	10.048,35 € (+ 207,45 €/additional brand)		695,26 €
variations regarding the analytical part herbal medicine ****	9.548,33 €	9.548,33 € (+ 207,45 €/additional brand)		695,26 €
d) Type II variations: clinical				
All clinical changes	6.865,43 €	6.865,43 € (+ 729,21 €/additional brand)		695,26 €
All clinical changes herbal medicine	7.954,12 €	7.954,12 € (+ 729,21 €/additional brand)		695,26 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 34.4)	1.018,83 €		not applicable	695,26 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

** For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

*** For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

**** If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

***** In case **3 or more** separate **analytical type II files** for the same product are filed at the same moment, the price is capped to 3x the contribution related to the analytical part of a type II variation.

Chapter 1 - Section 3 - Part 2 : MRP-variations, BE = CMS

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a) 1) Type IA variations	526,35 €	526,35 € (+ 201,16 €/additional brand)		526,35 €
a) 2) Type IA variations herbal medicine	605,10 €	605,10 € (+ 201,16 €/additional brand)	1 brand 605,10 €, ≥ 2 brands 695,26 €	
b) 1) Type IB variations	833,91 €	833,91 € (+ 201,16 €/additional brand)		695,26 €
b) 2) Type IB variations herbal medicine	530,18 €	530,18 € (+ 201,16 €/additional brand)	1 brand 530,18 €, ≥ 2 brands 695,26 €	
c) 1) Type II variations: analytical	742,81 €	742,81 € (+ 207,45 €/additional brand)		695,26 €
c) 2) Type II variations: analytical herbal medicine	782,62 €	782,62 € (+ 207,45 €/additional brand)		695,26 €
d) 1) Type II variations: clinical	1.682,90 €	1.682,90 € (+ 729,21 €/additional brand)		695,26 €
d) 2) Type II variations: clinical herbal medicine	1.903,38 €	1.903,38 € (+ 729,21 €/additional brand)		695,26 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	1.018,83 €		not applicable	695,26 €

If Belgium is acting as **RMS** : **specific contribution** (see infra).

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

** For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

*** For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

**** If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

Chapter 1 - Section 3 - Part 3 : MRP-variations, BE = RMS

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a) 1) Type IA variations	1.447,60 €	1.447,60 € (+ 201,16 €/additional brand)		695,26 €
a) 2) Type IA variations herbal medicine	847,87 €	847,87 € (+ 201,16 €/additional brand)		695,26 €
b) 1) Type IB variations	2.859,00 €	2.859,00 € (+ 201,16 €/additional brand)		695,26 €
b) 2) Type IB variations herbal medicine	2.730,76 €	2.730,76 € (+ 201,16 €/additional brand)		695,26 €
c) 1) Type II variations: analytical	8.216,96 €	8.216,96 € (+ 207,45 €/additional brand)		695,26 €
c) 2) Type II variations: analytical herbal medicine	7.670,31 €	7.670,31 € (+ 207,45 €/additional brand)		695,26 €
d) 1) Type II variations: clinical	13.028,95 €	13.028,95 € (+ 729,21 €/additional brand)		695,26 €
d) 2) Type II variations: clinical herbal medicine	13.606,31 €	13.606,31 € (+ 729,21 €/additional brand)		695,26 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	1.937,52 €		not applicable	695,26 €

For **herbal medicines** : the contributions concern renewals for MAD(s) and registration documents.

Contribution **per submitted dossier**, regardless of the number of MADs (with the exception of **worksharings** and **horizontal groupings**).

* For **vertical groupings**, only the contribution of the variation with the highest workload (II > IB > IA) is due.

** For **horizontal groupings**, the contribution of 1 type IA/adm. variation + fixed amount per additional MP group (brand) is due.

*** For **worksharings**, the contribution of the concerned variation + fixed amount per additional MP group (brand) is due.

**** If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount. [No reimbursement is foreseen in case of refusal of **IA** or **administrative variation**. The administrative fee for IA or administrative variations is only applicable in case of technical inadmissibility of the request (regular or herbal medicine).]

+ Chapter 3

a) Delayed closing of the dossier at request of the MAH

729,21 €

Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	2.209,06 €/licence
b) Renewal licence PI (RD* article 7, §1)	2.209,06 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	1.795,45 €/licence

* **Royal Decree** relating to **parallel imports** of medicines for human use and to **parallel distribution** of medicines for human and veterinary use (19/04/2001)

Remarks:

CMS	=	Concerned Member State
DCP	=	DeCentralised Procedure
MAD	=	Marketing Authorisation Document
MAH	=	Marketing Authorisation Holder
MRP	=	Mutual Recognition Procedure
PIL	=	Patient Information Leaflet
RMS	=	Reference Member State
RUP	=	Repeat-Use Procedure
SmPC	=	Summary of Product Characteristics

"The attention is drawn to the fact that the current text is merely **informal**, and it is by no means certain that its wordings and provisions correspond to the official **text** that is publically announced in the **Belgian Law Gazette**. The Federal Agency for Medicines and Health Products assumes no responsibility whatsoever as to such a lack of correspondence with the official text"