

Fees 2020 - Human medicinal products

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

		*
full/hybrid/bibliographic/biosimilar/fixed combination application MAD	32.110,04 €	570,52 €
generic/informed consent application MAD	27.947,21 €	570,52 €
application MAD or registration herbal medicine		
1) conform monograph	25.015,17 €	570,52 €
2) non-conform monograph	32.110,04 €	570,52 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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

		*
full/hybrid/bibliographic/biosimilar/fixed combination application MAD	51.562,39 €	570,52 €
generic/informed consent application MAD	43.303,79 €	570,52 €
application MAD or registration herbal medicine		
1) conform monograph	31.924,34 €	570,52 €
2) non-conform monograph	51.562,39 €	570,52 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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

		*
full/hybrid/bibliographic/biosimilar/fixed combination application MAD	10.925,51 €	570,52 €
generic/informed consent application MAD	9.398,62 €	570,52 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	9.398,62 €	570,52 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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 870,74 €

Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s)

1.035,80 €

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

		*
Renewal	5.952,80 €	570,52 €
Renewal herbal medicine	7.402,31 €	570,52 €

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)**

		*
Renewal	12.131,54 €	570,52 €
Renewal herbal medicine	12.181,05 €	570,52 €

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)**

		*
Renewal	1.079,14 €	570,52 €
Renewal herbal medicine	1.252,46 €	570,52 €

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

598,38 €

Chapter 1 - Section 3 - Part 1 : National variations

	*	**	***	****
a) 1) Type IA variations	556,08 €	556,08 € (+ 165,07 €/additional brand)		1 brand 556,08 €, ≥2 brands 570,52 €
a) 2) Type IA variations herbal medicine	462,20 €	462,20 € (+ 165,07 €/additional brand)		1 brand 466,20 €, ≥2 brands 570,52 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 556,08 €, respectively 462,20 €, is also due.				
Part 4 administrative variations	442,59 €	442,59 € (+ 171,26 €/additional brand)		1 brand 442,59 €, ≥2 brands 539,57 €
b) 1) Type IB variations	1.212,22 €	1.212,22 (+ 165,07 €/additional brand)		570,52 €
b) 1) Type IB variations herbal medicine	1.137,94 €	1.137,94 € (+ 165,07 €/additional brand)		570,52 €
c) Type II variations: analytical				
variations regarding the analytical part ****	7.315,65 €	7.315,65 € (+ 170,23 €/additional brand)		570,52 €
variations regarding the analytical part herbal medicine *****	9.274,81 €	9.274,26 € (+ 170,23 €/additional brand)		570,52 €
d) Type II variations: clinical				
All clinical changes	6.951,47 €	6.951,47 € (+ 598,38 €/additional brand)		570,52 €
All clinical changes herbal medicine	7.404,37 €	7.404,65 € (+ 598,38 €/additional brand)		570,52 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	772,73 €		not applicable	570,52 €

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

	*	**	***	****
a) 1) Type IA variations	360,06 €	360,06 € (+ 165,07 €/additional brand)		1 brand 360,06 €, 2 brands 525,12 €, ≥ 570,52 €
a) 2) Type IA variations herbal medicine	386,88 €	386,88 € (+ 165,07 €/additional brand)		1 brand 386,88 €, 2 brands 551,95 €, ≥ 570,52 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 360,06 €, respectively 386,88 €, is also due.				
b) 1) Type IB variations	357,99 €	357,99 € (+ 165,07 €/additional brand)		1 brand 357,99 €, 2 brands 523,06 €, ≥3 570,52 €
b) 2) Type IB variations herbal medicine	315,69 €	315,69 € (+ 165,07 €/additional brand)		1 brand 315,69 €, 2 brands 483,79 €, ≥3 570,52 €
c) 1) Type II variations: analytical	532,35 €	532,35 € (+ 170,23 €/additional brand)		1 brand 532,35 €, ≥2 brands 570,52 €
c) 2) Type II variations: analytical herbal medicine	962,55 €	962,55 € (+ 170,23 €/additional brand)		570,52 €
d) 1) Type II variations: clinical	1.354,59 €	1.354,59 € (+ 598,38 €/additional brand)		570,52 €
d) 2) Type II variations: clinical herbal medicine	1.663,07 €	1.659,04 € (+ 598,38 €/additional brand)		570,52 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	772,73 €		not applicable	570,52 €

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

	*	**	***	****
a) 1) Type IA variations	592,19 €	592,19 € (+ 165,07 €/additional brand)		570,52 €
a) 2) Type IA variations herbal medicine	592,19 €	592,19 € (+ 165,07 €/additional brand)		570,52 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 592,19 € is also due.				
b) 1) Type IB variations	1.844,65 €	1.844,65 € (+ 165,07 €/additional brand)		570,52 €
b) 2) Type IB variations herbal medicine	1.945,75 €	1.945,75 € (+ 165,07 €/additional brand)		570,52 €
c) 1) Type II variations: analytical	6.070,41 €	6.070,41 € (+ 170,23 €/additional brande)		570,52 €
c) 2) Type II variations: analytical herbal medicine	6.070,41 €	6.070,41 € (+ 170,23 €/additional brand)		570,52 €
d) 1) Type II variations: clinical	10.221,90 €	10.221,90 € (+ 598,38 €/additional brand)		570,52 €
d) 2) Type II variations: clinical herbal medicine	10.221,90 €	10.221,90 € (+ 598,38 €/additional brand)		570,52 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	772,73 €		not applicable	570,52 €

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 598,38 €

Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	1.069,85 €/licence
b) Renewal licence PI (RD* article 7, §1)	1.069,85 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	919,23 €/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

All fees have to be paid in advance and the **proof of payment** is required (in part IA / module 1) before an application can be accepted.

Fees payable on account number: 679-0021942-20

IBAN-CODE: **BE28 6790 0219 4220**

Swift code: PCHQBEBB

"The attention is drawn to the fact that the current text is merely **informal**, and it is by no means certain that its current wordings and provisions correspond to the eventual **final text** that will be 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 final text"