

Fees 2023 - 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	43.356,72 €	658,91 €
generic/informed consent application MAD	32.891,81 €	658,91 €
application MAD or registration herbal medicine		
1) conform monograph	25.694,69 €	658,91 €
2) non-conform monograph	43.356,72 €	658,91 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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	62.957,66 €	658,91 €
generic/informed consent application MAD	51.397,39 €	658,91 €
application MAD or registration herbal medicine		
1) conform monograph	34.379,77 €	658,91 €
2) non-conform monograph	62.957,66 €	658,91 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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	14.655,22 €	658,91 €
generic/informed consent application MAD	12.887,97 €	658,91 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	12.887,97 €	658,91 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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 1.005,64 €

Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s) 1.372,35 €

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

		*
Renewal	7.696,70 €	658,91 €
Renewal herbal medicine	5.087,66 €	658,91 €

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	15.466,64 €	658,91 €
Renewal herbal medicine	10.364,18 €	658,91 €

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	1.198,04 €	658,91 €
Renewal herbal medicine	1.467,35 €	658,91 €

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 691,07 €

Chapter 1 - Section 3 - Part 1 : National variations

	*	**	***	****
a) 1) Type IA variations	641,46 €	641,46 € (+ 190,64 €/additional brand)		641,46 €
a) 2) Type IA variations herbal medicine	1.010,70 €	1.010,70 € (+ 190,64 €/additional brand)		658,91 €
Part 4 administrative variations	708,26 €	708,26 € (+ 197,79 €/additional brand)		658,91 €
b) 1) Type IB variations	1.189,44 €	1.189,44 (+ 190,64 €/additional brand)		658,91 €
b) 1) Type IB variations herbal medicine	1.893,13 €	1.893,13 € (+ 190,64 €/additional brand)		658,91 €
c) Type II variations: analytical				
variations regarding the analytical part ****	9.522,94 €	9.522,94 € (+ 196,60 €/additional brand)		658,91 €
variations regarding the analytical part herbal medicine *****	9.049,06 €	9.049,06 € (+ 196,60 €/additional brand)		658,91 €
d) Type II variations: clinical				
All clinical changes	6.506,44 €	6.506,44 € (+ 691,07 €/additional brand)		658,91 €
All clinical changes herbal medicine	7.538,20 €	7.538,20 € (+ 691,07 €/additional brand)		658,91 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 34.4)	965,56 €		not applicable	658,91 €

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	498,82 €	498,82 € (+ 190,64 €/additional brand)		498,82 €
a) 2) Type IA variations herbal medicine	573,47 €	573,47 € (+ 190,64 €/additional brand)		1 brand 573,47 €, ≥2 brands 658,91 €
b) 1) Type IB variations	790,31 €	790,31 € (+ 190,64 €/additional brand)		658,91 €
b) 2) Type IB variations herbal medicine	502,47 €	502,47 € (+ 190,64 €/additional brand)		1 brand 502,47 €, ≥2 brands 658,91 €
c) 1) Type II variations: analytical	703,97 €	703,97 € (+ 196,60 €/additional brand)		658,91 €
c) 2) Type II variations: analytical herbal medicine	741,69 €	741,69 € (+ 196,60 €/additional brand)		658,91 €
d) 1) Type II variations: clinical	1.594,90 €	1.594,90 € (+ 691,07 €/additional brand)		658,91 €
d) 2) Type II variations: clinical herbal medicine	1.803,86 €	1.803,86 € (+ 691,07 €/additional brand)		658,91 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	965,56 €		not applicable	658,91 €

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	1.371,90 €	1.371,90 € (+ 190,64 €/additional brand)		658,91 €
a) 2) Type IA variations herbal medicine	803,53 €	803,53 € (+ 190,64 €/additional brand)		658,91 €
b) 1) Type IB variations	2.709,50 €	2.709,50 € (+ 190,64 €/additional brand)		658,91 €
b) 2) Type IB variations herbal medicine	2.589,04 €	2.589,04 € (+ 190,64 €/additional brand)		658,91 €
c) 1) Type II variations: analytical	7.787,30 €	7.787,30 € (+ 196,60 €/additional brand)		658,91 €
c) 2) Type II variations: analytical herbal medicine	7.269,24 €	7.269,24 € (+ 196,60 €/additional brand)		658,91 €
d) 1) Type II variations: clinical	12.347,69 €	12.347,69 € (+ 691,07 €/additional brand)		658,91 €
d) 2) Type II variations: clinical herbal medicine	12.894,85 €	12.894,85 € (+ 691,07 €/additional brand)		658,91 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	1.836,20 €	not applicable		658,91 €

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 691,07 €

Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	2.093,55 €/licence
b) Renewal licence PI (RD* article 7, §1)	2.093,55 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	1.701,56 €/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"