

Fees 2022 - 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	38.963,58 €	592,15 €
generic/informed consent application MAD	29.559,03 €	592,15 €
application MAD or registration herbal medicine		
1) conform monograph	23.091,16 €	592,15 €
2) non-conform monograph	38.963,58 €	592,15 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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	56.578,44 €	592,15 €
generic/informed consent application MAD	46.189,52 €	592,15 €
application MAD or registration herbal medicine		
1) conform monograph	30.896,22 €	592,15 €
2) non-conform monograph	56.578,44 €	592,15 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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	13.170,27 €	592,15 €
generic/informed consent application MAD	11.582,09 €	592,15 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	11.582,09 €	592,15 €

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* If the application could not be accepted (invalidation) or if the application has been withdrawn within the legal validation period, fees will be refunded less this amount.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 903,74 €

Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s) 1.233,30 €

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

		*
Renewal	6.178,42 €	592,15 €
Renewal herbal medicine	4.572,15 €	592,15 €

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	12.591,33 €	592,15 €
Renewal herbal medicine	9.314,02 €	592,15 €

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	1.120,04 €	592,15 €
Renewal herbal medicine	1.318,67 €	592,15 €

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 621,05 €

Chapter 1 - Section 3 - Part 1 : **National variations**

	*	**	***	****
a) 1) Type IA variations	576,46 €	576,46 € (+ 171,32 €/additional brand)		576,46 €
a) 2) Type IA variations herbal medicine	908,29 €	908,29 € (+ 171,32 €/additional brand)		592,15 €
Part 4 administrative variations	636,49 €	903,14 € (+ 177,75 €/additional brand)		592,15 €
b) 1) Type IB variations	1.068,92 €	1.068,92 (+ 171,32 €/additional brand)		592,15 €
b) 1) Type IB variations herbal medicine	1.701,31 €	1.701,31 € (+ 171,32 €/additional brand)		592,15 €
c) Type II variations: analytical				

variations regarding the analytical part *****	8.558,02 €	8.558,02 € (+ 176,68 €/additional brand)	592,15 €
variations regarding the analytical part herbal medicine *****	8.132,16 €	8.132,16 € (+ 176,68 €/additional brand)	592,15 €
d) Type II variations: clinical			
All clinical changes	5.847,17 €	5.847,17 € (+ 621,05 €/additional brand)	592,15 €
All clinical changes herbal medicine	6.774,39 €	6.774,39 € (+ 621,05 €/additional brand)	592,15 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 34.4)	867,72 €	not applicable	592,15 €

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	448,28 €	1 brand 448,28 €, ≥2 brands 592,15 €		448,28 €
a) 2) Type IA variations herbal medicine	515,36 €	515,36 € (+ 171,32 €/additional brand)	1 brand 515,36 €, ≥2 brands 592,15 €	
b) 1) Type IB variations	710,23 €	710,23 € (+ 171,32 €/additional brand)		592,15 €
b) 2) Type IB variations herbal medicine	451,56 €	451,56 € (+ 171,32 €/additional brand)	1 brand 451,56 €, ≥2 brands 592,15 €	
c) 1) Type II variations: analytical	632,64 €	632,64 € (+ 176,68 €/additional brand)	1 brand 552,52 €, 2 brands 592,15 €	
c) 2) Type II variations: analytical herbal medicine	666,54 €	666,54 € (+ 176,68 €/additional brand)		592,15 €
d) 1) Type II variations: clinical	1.492,03 €	1.492,03 € (+ 621,05 €/additional brand)		592,15 €
d) 2) Type II variations: clinical herbal medicine	1.621,08 €	1.621,08 € (+ 621,05 €/additional brand)		592,15 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	867,72 €	not applicable		592,15 €

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	1.232,89 €	1.232,89 € (+ 171,32 €/additional brand)		592,15 €
a) 2) Type IA variations herbal medicine	722,11 €	722,11 € (+ 171,32 €/additional brand)		592,15 €
b) 1) Type IB variations	1.914,56 €	1.914,56 € (+ 171,32 €/additional brand)		592,15 €
b) 2) Type IB variations herbal medicine	2.019,50 €	2.019,50 € (+ 171,32 €/additional brand)		592,15 €
c) 1) Type II variations: analytical	6.998,25 €	6.998,25 € (+ 176,68 €/additional brand)		592,15 €
c) 2) Type II variations: analytical herbal medicine	6.532,68 €	6.532,68 € (+ 176,68 €/additional brand)		592,15 €
d) 1) Type II variations: clinical	11.096,55 €	11.096,55 € (+ 621,05 €/additional brand)		592,15 €
d) 2) Type II variations: clinical herbal medicine	11.588,27 €	11.588,27 € (+ 621,05 €/additional brand)		592,15 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC (Notification art. 61.3)	1.650,15 €		not applicable	592,15 €

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 **621,05 €**

Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	1.881,42 €/licence
b) Renewal licence PI (RD* article 7, §1)	1.881,42 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	1.529,15 €/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 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"