

Fees 2021 - 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	32.400,23 €	575,68 €
generic/informed consent application MAD	28.199,78 €	575,68 €
application MAD or registration herbal medicine		
1) conform monograph	25.241,24 €	575,68 €
2) non-conform monograph	32.400,23 €	575,68 €

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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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	52.028,37 €	575,68 €
generic/informed consent application MAD	43.695,13 €	575,68 €
application MAD or registration herbal medicine		
1) conform monograph	32.212,85 €	575,68 €
2) non-conform monograph	52.028,37 €	575,68 €

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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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	11.024,24 €	575,68 €
generic/informed consent application MAD	9.483,55 €	575,68 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	9.483,55 €	575,68 €

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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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 **878,61 €**

Chapter 11 - Section 2

Application for reglementary advice concerning umbrella brand(s)

1.045,17 €

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

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Renewal	6.006,60 €	575,68 €
Renewal herbal medicine	7.469,21 €	575,68 €

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	12.241,17 €	575,68 €
Renewal herbal medicine	12.291,14 €	575,68 €

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	1.088,89 €	575,68 €
Renewal herbal medicine	1.263,78 €	575,68 €

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

603,78 €

Chapter 1 - Section 3 - Part 1 : National variations

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a) 1) Type IA variations	561,10 €	561,10 € (+ 166,56 €/additional brand)		1 brand 561,10 €, ≥2 brands 575,68 €
a) 2) Type IA variations herbal medicine	466,37 €	466,37 € (+ 166,56 €/additional brand)		1 brand 470,42 €, ≥2 brands 575,68 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 561,10 €, respectively 466,37 €, is also due.				
Part 4 administrative variations	446,59 €	446,59 € (+ 172,81 €/additional brand)		1 brand 446,59 €, ≥2 brands 544,45 €
b) 1) Type IB variations	1.223,18 €	1.223,18 (+ 166,56 €/additional brand)		575,68 €
b) 1) Type IB variations herbal medicine	1.148,23 €	1.148,18 € (+ 166,56 €/additional brand)		575,68 €
c) Type II variations: analytical				
variations regarding the analytical part *****	7.381,76 €	7.381,76 € (+ 171,77 €/additional brand)		575,68 €
variations regarding the analytical part herbal medicine *****	9.358,63 €	9.358,63 € (+ 171,27 €/additional brand)		575,68 €
d) Type II variations: clinical				
All clinical changes	7.014,29 €	7.014,29 € (+ 603,78 €/additional brand)		575,68 €
All clinical changes herbal medicine	7.471,29 €	7.471,29 € (+ 603,78 €/additional brand)		575,68 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	779,71 €		not applicable	575,68 €

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	363,31 €	363,31 € (+ 166,56 €/additional brand)		1 brand 363,31 €, 2 brands 529,87 €, ≥ 575,68 €
a) 2) Type IA variations herbal medicine	390,38 €	390,38 € (+ 166,56 €/additional brand)		1 brand 390,38 €, 2 brands 556,94 €, ≥ 575,68 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 363,31 €, respectively 390,38 €, is also due.				
b) 1) Type IB variations	361,23 €	361,2 € (+ 166,56 €/additional brand)		1 brande 361,23 €, 2 brands 527,79 €, ≥3 575,68 €
b) 2) Type IB variations herbal medicine	318,55 €	318,55 € (+ 166,56 €/additional brand)		1 brand 318,55 €, 2 brands 488,16 €, ≥3 575,68 €
c) 1) Type II variations: analytical				
	537,16 €	537,16 € (+ 171,77 €/additional brand)		1 brand 537,16 €, ≥2 brands 575,68 €
c) 2) Type II variations: analytical herbal medicine				
	971,26 €	971,265 € (+ 171,77 €/additional brand)		575,68 €
d) 1) Type II variations: clinical				
	1.366,84 €	1.366,84 € (+ 603,78 €/additional brand)		575,68 €
d) 2) Type II variations: clinical herbal medicine				
	1.678,10 €	1.678,10 € (+ 603,78 €/additional brand)		575,68 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	779,71 €		not applicable	575,68 €

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	597,54 €	597,54 € (+ 166,56 €/additional brand)		575,68 €
a) 2) Type IA variations herbal medicine	597,54 €	597,54 € (+ 166,56 €/additional brand)		575,68 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 597,54 € is also due.				
b) 1) Type IB variations	1.861,32 €	1.861,32 € (+ 166,56 €/additional brand)		575,68 €
b) 2) Type IB variations herbal medicine	1.963,33 €	1.963,33 € (+ 166,56 €/additional brand)		575,68 €
c) 1) Type II variations: analytical	6.125,27 €	6.125,27 € (+ 171,77 €/additional brand)		575,68 €
c) 2) Type II variations: analytical herbal medicine	6.125,27 €	6.125,27 € (+ 171,77 €/additional brand)		575,68 €
d) 1) Type II variations: clinical	10.314,27 €	10.314,27 € (+ 603,78 €/additional brand)		575,68 €
d) 2) Type II variations: clinical herbal medicine	10.314,27 €	10.314,27 € (+ 603,78 €/additional brand)		575,68 €
Part 5 e) change(s) to the PIL and/or labelling without impact on SmPC	779,71 €	not applicable		575,68 €

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 603,78 €

Chapter 6 : Parallel import

a) New application licence PI (RD* article 4) <u>or</u> modification licence PI (RD* article 7, §§ 2 and 3)	1.079,52 €/licence
b) Renewal licence PI (RD* article 7, §1)	1.079,52 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	927,54 €/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"