

Fees 2022 - 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	33 327,05 €	592,15 €
generic/informed consent application MAD	29 006,45 €	592,15 €
application MAD or registration herbal medicine		
1) conform monograph	25 963,28 €	592,15 €
2) non-conform monograph	33 327,05 €	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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	53 516,66 €	592,15 €
generic/informed consent application MAD	44 945,05 €	592,15 €
application MAD or registration herbal medicine		
1) conform monograph	33 134,31 €	592,15 €
2) non-conform monograph	53 516,66 €	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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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)

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full/hybrid/bibliographic/biosimilar/fixed combination application MAD	11 339,59 €	592,15 €
generic/informed consent application MAD	9 754,83 €	592,15 €
application MAD or registration herbal medicine (regardless of conformity to a monograph)	9 754,83 €	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* If the application could not be accepted (**invalidation**) or if the application has been **withdrawn** within the legal validation period, fees will be refunded less this amount.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) 1 075,07 €

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

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Renewal	6 178,42 €	592,15 €
Renewal herbal medicine	7 682,87 €	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)**

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Renewal	12 591,33 €	592,15 €
Renewal herbal medicine	12 642,73 €	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	1 299,93 €	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	577,15 €	577,15 € (+ 171,32 €/additional brand)		1 brand 577,15 €, ≥2 brands 592,15€
a) 2) Type IA variations herbal medicine	479,71 €	479,71 € (+ 171,32 €/additional brand)		1 brand 483,88 €, ≥2 brands 592,15 €
For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 577,15 € , respectively 479,71 € , is also due.				
Part 4 administrative variations	459,36 €	459,36 € (+ 177,75 €/additional brand)		1 brand 459,36 €, ≥2 brands 560,02 €
b) 1) Type IB variations	1 258,17 €	1258,17 (+ 171,32 €/additional brand)		592,15 €
b) 1) Type IB variations herbal medicine	1 181,08 €	1181,08 € (+ 171,32 €/additional brand)		592,15 €

c) Type II variations: analytical			
variations regarding the analytical part ****	7 592,92 €	7592,92 € (+ 176,68 €/additional brand)	592,15 €
variations regarding the analytical part herbal medicine *****	9 626,34 €	9626,34 € (+ 176,17 €/additional brand)	592,15 €
d) Type II variations: clinical			
All clinical changes	7 214,94 €	7214,94 € (+ 621,05 €/additional brand)	592,15 €
All clinical changes herbal medicine	7 685,01 €	7685,01 € (+ 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)	802,01 €	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	373,70 €	373,70 € (+ 171,32 €/additional brand)		1 brand 373,70 €, 2 brands 545,03 €, ≥ 592,15 €
a) 2) Type IA variations herbal medicine	401,55 €	401,55 € (+ 171,32 €/additional brand)		1 brand 401,55 €, 2 brands 572,87 €, ≥ 592,15 €
For variations type IA nr. A.1, A.4, A.5a and A.5b the contribution of 373,70 €, respectively 401,55 €, is also due.				
b) 1) Type IB variations	371,56 €	371,56 € (+ 171,32 €/additional brand)		1 brand 371,56 €, 2 brands 542,89 €, ≥ 592,15 €
b) 2) Type IB variations herbal medicine	327,66 €	327,66 € (+ 171,32 €/additional brand)		1 brand 327,66 €, 2 brands 502,12 €, ≥ 592,15 €
c) 1) Type II variations: analytical	552,53 €	552,53 € (+ 176,68 €/additional brand)		1 brand 552,53 €, ≥ 2 brands 592,15 €
c) 2) Type II variations: analytical herbal medicine	999,04 €	999,04 € (+ 176,68 €/additional brand)		592,15 €
d) 1) Type II variations: clinical	1 405,94 €	1405,94 € (+ 621,05 €/additional brand)		592,15 €
d) 2) Type II variations: clinical herbal medicine	1 726,10 €	1726,10 € (+ 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)	802,01 €	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	614,63 €	614,63 € (+ 171,32 €/additional brand)		592,15 €
a) 2) Type IA variations herbal medicine	614,63 €	614,63 € (+ 171,32 €/additional brand)		592,15 €

For variations type IA nr. A.1 , A.4 , A.5a and A.5b the contribution of 614,63 € is also due.			
b) 1) Type IB variations	1 914,56 €	1914,56 € (+ 171,32 €/additional brand)	592,15 €
b) 2) Type IB variations herbal medicine	2 019,49 €	2019,49 € (+ 171,32 €/additional brand)	592,15 €
c) 1) Type II variations: analytical	6 300,49 €	6300,49 € (+ 176,68 €/additional brand)	592,15 €
c) 2) Type II variations: analytical herbal medicine	6 300,49 €	6300,49 € (+ 176,68 €/additional brand)	592,15 €
d) 1) Type II variations: clinical	10 609,31 €	10609,31 € (+ 621,05 €/additional brand)	592,15 €
d) 2) Type II variations: clinical herbal medicine	10 609,31 €	10609,31 € (+ 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)	802,01 €	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)	1110,40 €/licence
b) Renewal licence PI (RD* article 7, §1)	1110,40 €/licence
c) Modification licence PI (<u>except</u> RD* article 7, §§ 2 and 3)	954,07 €/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"